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A How-to Guide for Conducting a Statewide Roadside Survey of Alcohol and Other Drugs

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16. Abstract Having valid and reliable estimates of the prevalence of alcohol and other drug use among drivers on the roadway are important components of addressing impaired driving. Roadside collections of biological samples are an effective way to measure drug prevalence among drivers in a State. Prevalence refers to the proportion of drivers on the road who test positive for alcohol or other drugs. While presence of a drug does not always mean a driver is impaired, the collection of biological specimens through roadside surveys allows for the quantitative determination of alcohol and drug levels in drivers' systems. NHTSA has conducted several voluntary and anonymous National Roadside Surveys and also worked with Washington State to conduct a statewide survey before and after legalization of the recreational use of cannabis in that State. If a State is interested in conducting its own statewide roadside survey, this <i>How-to Guide</i> draws on these past experiences to provide start-to-finish guidance on how to develop and implement a statewide survey of alcohol and other drug prevalence among drivers. The guide includes information on how to develop a study plan, budget, and conduct specimen collection. It also contains information on the research questions that can be addressed, personnel and equipment needed, and issues that may arise (e.g., how to handle an impaired driver). This guide is intended as a primer for State officials, project managers, and researchers on the components of a quality statewide study. After reading this guide, a study manager will understand the scope of activities a comprehensive study must include, and the importance of including experienced professionals in the data collection and analysis activities.					
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Introduction

Having reliable estimates of the prevalence of alcohol and other drugs among drivers are important parts of a program to address impaired driving. Roadside collections of biological samples are the best way to measure drug prevalence in drivers on the road and have been a valuable part of previous efforts to understand the extent of alcohol- and other drug-involved driving. For decades the National Highway Traffic Safety Administration has supported efforts to estimate the population-level prevalence of drinking and driving using such studies. The studies have now expanded to include other drugs that have the potential to impair driving performance and affect highway safety.

Roadside studies provide objective measures of the number and proportion of drivers with alcohol and other drugs in their systems when they are driving. While presence of a drug does not always mean that a driver is impaired, the collection of biological specimens through roadside surveys allows for the quantitative determination of alcohol and drug levels in drivers' systems. The collection of biological specimens from randomly sampled drivers on active roadways serves as the most valid approach to estimating how many drivers are on the road with potentially impairing drugs in their systems during a given time period.

Approaches to measuring alcohol and other drug prevalence on the road vary in key factors such as sampling design, degree of rigor, and cost. NHTSA has published extensive descriptions of methodology for on-road data collection for its roadside studies (Kelley-Baker et al., 2016; Lacey et al., 2007; Ramirez et al., 2016) and its "Virginia Beach" crash risk study (Lacey et al., 2016). Much of what is presented in this document comes from NHTSA's experience with the National Roadside Surveys (NRS) of drugs and alcohol and NHTSA's work with Washington State for its statewide roadside study of drug use before and after the legalization of the recreational use of cannabis/marijuana¹ in the State. Some aspects of roadside sampling are flexible because different approaches may be required depending on the research questions a study seeks to answer. The fundamentals described in this guide; however, should be followed to the extent feasible and resources allow, to provide the most valid estimate of alcohol and other drug prevalence among drivers in the locale being studied.

A first step is to ask the question, *Is a roadside study the right approach for what the State needs to know?* If the answer is *Yes*, the next question is, *What is the best methodology to answer the specific research questions?* This document is designed to help answer these questions and provides step-by-step instructions to prepare the reader to conduct a roadside study.

¹ The terms "cannabis" and "marijuana" are often used interchangeably, but are not fully synonymous. Cannabis refers to the *Cannabis sativa/indica/ruderalis* plants and broadly covers all products derived from them. Marijuana is a non-scientific term usually referring to the parts of the plants that contain the psychoactive compound tetrahydrocannabinol (THC). This guide uses the terms cannabis and cannabinoids to refer to the potentially impairing chemical compounds of interest, including what might (less precisely) be referred to as marijuana.

Is a Roadside Prevalence Study the Right Approach?

Before delving into the “How-to” portion of this guide, it is vital to review the concept of prevalence, the inherent limitations of a prevalence study, and whether this type of study is the right approach to answer the research questions of interest.

The National Institute of Mental Health (NIMH, n.d.) provides a good definition of prevalence and additional information on the topic. According to NIMH, *prevalence is the proportion of a population who have a specific characteristic in a given time period*. For a representative sample of a population of interest, prevalence is calculated with the simple equation shown below.

$$\text{Prevalence} = \frac{\text{Number of people in sample with characteristic}}{\text{Total number of people in sample}}$$

For the type of study described in this guide, the characteristic of interest is whether a driver tests positive for the presence of alcohol or another potentially impairing drug. Because it is not reasonable to get a biological specimen from every driver on the road in a State, a study must collect information from a smaller set of drivers (the “sample”) to estimate drugged driving prevalence among the larger population. This guide discusses how to select a representative sample and how to mathematically weight the data to make valid inferences about the entire driving population in a State.

Roadside studies can also be useful for collecting ancillary information from drivers such as opinions and knowledge about laws, awareness of highway safety campaigns, and knowledge of other highway safety topics. However, if the research questions do not involve determining the prevalence of drug use among drivers on roadways, there are more efficient and less costly approaches available than the use of a roadside survey to collect such information.

Table 1 addresses whether a statewide prevalence study involving the collection of biological samples is the right approach for answering certain research questions. It lists common research topics of interest and provides basic answers as to whether a roadside study is an appropriate way to answer them. As shown in the table, there are questions that a statewide prevalence study is not capable of answering.

Table 1. Is a Roadside Study the Right Approach for the Question of Interest?

Question	Is a roadside survey the right approach?	Notes
What is the prevalence of alcohol or drugs in persons driving on a set of public roads?	Yes	<ul style="list-style-type: none"> • A roadside study is designed to provide a snapshot of the prevalence of alcohol- and drug-positive drivers on sampled roads. • The sampling approach dictates whether the data are representative of all drivers in the area of interest. • Data collection can be repeated to examine changes over time.
Is our impaired driving countermeasure program working?	Yes, with caveats	<ul style="list-style-type: none"> • A study conducted with a pre/post design and control sites can inform if a countermeasure impacted the prevalence of alcohol- or drug-positive driving in the target area. • Intervention and control sites must be carefully matched to ensure the samples are equivalent for comparison. • It is difficult to attribute observed changes in the target area solely to the countermeasure program because other factors can be at play (e.g., economic shifts, population shifts, new synthetic drugs, other simultaneous program activities).
What is alcohol and other drug <i>involvement</i> in crashes?	No	<ul style="list-style-type: none"> • A statewide prevalence study does not include crash-involved drivers. • Answering this question requires going to active crash scenes, hospitals for seriously injured drivers, or to morgues for fatally-injured drivers.
What is the <i>crash risk</i> of alcohol and other drugs?	No	<ul style="list-style-type: none"> • No statement about crash risk can be made with a prevalence study alone. • Statewide prevalence data could be used for risk estimates if drug data are also collected from a representative sample of crash drivers, but the risk estimates could be severely biased. • A matched case-control study is best for a crash risk study. • Answering this question requires going to active crash scenes, hospitals for seriously injured drivers, or to morgues for fatally-injured drivers.

Question	Is a roadside survey the right approach?	Notes
Do residents support alcohol and drugged driving laws?	No	<ul style="list-style-type: none"> • Staff can gather the opinions of drivers participating in the roadside study, but they may not reside in the area of interest. • Time is limited with roadside studies that reduce how many questions researchers can ask. • Less costly approaches are available to answer this question.

If the table above suggests a roadside study may be appropriate, it is important to consider the pros and cons of the approach listed in Table 2.

Table 2. Pros and Cons of a Roadside Study

Pros
<ul style="list-style-type: none"> • Gathers data from people who are of most interest – drivers on the road – and specifically <i>when</i> they are driving • The sample can be representative of the entire State • Drivers volunteer to participate; drivers who are not interested do not participate • Privacy is protected through anonymous data collection • Data can be collected throughout the week (but most typically on weekends), day and night • Drivers are recruited from a variety of urban, suburban, and rural environments • Can collect breath samples, oral fluid, blood, questionnaire data, or any combination • Collection of data can be broadened to examine differences in self-reported behaviors, opinions, or attitudes of drug-positive vs. drug-negative drivers
Cons
<ul style="list-style-type: none"> • Costs for planning, developing the sampling frame, supplies, data collectors, laboratory fees, shipping, participant payments, travel, data analysis, and report writing are substantial • No statements about crash risk or drug involvement in crashes can be made • In some locations, or at certain data collection times, participation may be low

Step-by-Step Guidance

This section provides information on how to conduct a statewide roadside study to estimate the prevalence of alcohol and other drugs among a driving population. It is intended as a primer for state officials, project managers, and researchers on the various components of a quality statewide study. After reading this guide, the reader should understand the scope of activities a comprehensive study should include and the need to acquire data collection and analysis support from qualified professionals.

This guide provides broad recommendations and ideas but cannot possibly address all considerations necessary for developing a roadside study. The reader should treat this guide as a starting point, but the parameters and protocols appropriate for a given scenario should be developed in close consultation with experts. Federal, State, and local laws and regulations may affect how some of the recommendations in this guide may be implemented for a given location.

Step 1. Define Study Objectives and Research Questions

A vital first step is to define the objectives and research questions given the situation in the State (see Tables 3 and 4 for examples). Generally, the objective of a roadside study is to learn the prevalence of alcohol and other drugs in the systems of drivers on the road. This can be accomplished by obtaining and analyzing biological samples (i.e., breath, oral fluid, blood) from drivers to estimate the prevalence of select over-the-counter, prescription, and illegal drugs that may have impairing effects. The approach allows for the collection of data from a representative sample of drivers across the studied locale.

The type of biological samples to be used in a study also depends on the nature of the research questions to be addressed. For example, using blood allows for the most accurate representation of drugs in a driver's system at the time the blood was drawn. Obtaining blood samples, however, requires venipuncture. Study participants may be more willing to provide oral fluid samples because they are less invasive. An oral fluid drug concentration generally mimics that found in blood, which makes it a good option for a prevalence study that is mostly interested in making a drug present/absent determination. If the study is only interested in alcohol, a breath sample is all that is needed. NHTSA's prior roadside efforts included the collection of all three types of samples to gather as much information as possible and saw high participation rates by drivers, but collecting three types of samples may not be necessary for every study.

Table 3. Sample Objective 1

Objective: To measure changes in statewide prevalence of cannabis use by drivers after legalization of recreational use.	
Research Question	Notes
Did the prevalence of cannabis use by drivers change after legalization?	<ul style="list-style-type: none"> • Requires the collection of oral fluid and/or blood samples from drivers on an equivalent set of roads before and after legalization • Baseline data must be collected before sales begin • Two baseline measures, with one close to the date of initial sales is beneficial • Multiple post-legalization measurements can be taken to track changes over time
Do prevalence rates differ based on time of day or day of week?	<ul style="list-style-type: none"> • If a representative study is desired, a roadside study should include measurements across a variety of times of day and days of the week • Daytime and nighttime prevalence rates may be impacted differentially
Were there changes in rates of BrAC-positive drivers after legalization of recreational use?	<ul style="list-style-type: none"> • A breath alcohol concentration (BrAC) can be taken with relative ease² • Rates of BrAC-positive drivers with and without cannabis positive samples can be compared from before and after the law change
Are drivers self-reporting any changes in opinions or driving behaviors after legalization?	<ul style="list-style-type: none"> • A survey could ask about self-reported cannabis use, driving habits, and opinions about driving after consumption • Results can be compared for cannabis positive and negative drivers and any demographic or other measured variables (e.g., BrAC)

² If collecting breath samples is a concern due to an issue such as virus transmission during the COVID-19 public health emergency, blood alcohol concentration (BAC) can also be determined by an oral fluid or blood sample.

Table 4. Sample Objective 2

Objective: To measure the prevalence of poly (multiple) drug use among drivers.	
Research Question	Notes
What combinations of drugs are found in drivers' systems?	<ul style="list-style-type: none"> • Toxicology lab testing is available for almost all known drugs of interest • Each test adds cost; however, a lab may be willing to negotiate prices, especially if there will be a large number of specimens (and for a large number of drugs) • Alcohol testing should always be included via breath, oral fluid, or blood test • Some drugs have synergistic effects where even small amounts of two or more drugs together can lead to severe impairment
Does poly drug use prevalence differ based on time of day or day of week?	<ul style="list-style-type: none"> • Driver studies generally focus on night and weekend data collection because of the higher crash fatality rates during those times • Data collection can include different days and times but costs increase with each additional sampling period

Step 2. Develop a Budget

Ideally, a study is first designed to address the desired research questions, and then the budget is determined based on the estimated planning, personnel, toxicology, and reporting costs associated with the preferred design. The proposed budget would then be presented to a funding agency for consideration. Often, however, someone (e.g., State agency, Federal grant) dictates that a certain amount of money is available for the project before the study plans are fully developed. When this happens, the study must be designed to fit within the constraints of the budget and it may, or may not, be capable of answering all of the research questions of interest or capturing the desired sample size.

Small-scale studies in single counties can be affordable, but a statewide prevalence study of drugged driving has a number of expenses that increase the costs quickly. Below is an example study outline and budget estimate for collecting data a single time statewide. If there are multiple data collection time frames (or “waves”) over time, the planning costs for each wave will be significantly reduced but basic data collection costs will remain similar for each wave.

Example Study Outline

1. Preliminary Planning

- a. Select drugs of interest and join with laboratory (budget examples assume a drug panel similar to that used in Washington State’s roadside study)
- b. Develop a data collection and analysis plan:
 - i. Identify 30 study sampling sites across six counties
 - ii. Create plans for roadside collection of oral fluid/blood and breath test
 - iii. Use two teams operating simultaneously (1 team leader, 1 safety officer, 5 data collectors per team) to complete data collection over 3 weekends

- iv. Develop demographic observation plans and survey items
- v. Use computer tablets for entering data
2. Submit protocols for institutional review board review
3. Coordinate with data collection sites to determine specific locations
4. Train data collectors
5. Collect biological samples and send to toxicology laboratory for analysis
6. Merge, clean, and analyze data
7. Write report on findings.

Example Budget Estimates

Table 5 summarizes major labor and other costs for the study described above to collect oral fluid samples during one wave at 30 locations as was done in Washington State's roadside study. Table 6 provides estimates for a study that is collecting blood. The costs are high-level estimates for a private research firm or university to conduct the study. Costs can vary significantly based on level of effort, not only for planning, data collection, and drug testing, but also for the amount of detail in data analyses and report writing. These are only ballpark figures to provide a sense of the scope and types of costs. Obtaining a blood sample is substantially more expensive as it requires having a phlebotomist on every data collection team; additional supplies for obtaining, storing, and packaging blood samples; and more expensive laboratory analyses.

Table 5. Example Budget for One-Time Statewide Study (Oral Fluid)

Labor Cost Item	Estimated Cost	Materials and Other Cost Items	Estimated Cost
Preliminary Planning	\$25,000	Participant Payments (N = 1,000)	\$20,000
Submit to IRB	\$3,000	Oral Fluid Kits & Lab Fees (N = 1,000)	\$80,000
Coordinate with sites	\$3,000	Training Development Supplies	\$2,000
Train data collectors		Rental Vans for Data Collectors	\$4,000
Manager(s) (1 x 2 teams = 2)	\$1,000	On-Site Storage for Equipment	\$2,000
Safety Officers (1 x 2 teams = 2)	\$1,000	Tablet Programming	\$1,000
Local data collector (5 x 2 teams = 10)	\$5,000	Data Collection Supplies	\$8,000
Collect data		Preliminary Breath Test Devices	\$5,000
Manager(s) (1 x 2 teams = 2)	\$20,000	Travel and lodging	\$50,000
Safety Officers (1 x 2 teams = 2)	\$20,000		
Local data collector (5 x 2 teams = 10)	\$70,000	Total Other Costs	\$172,000
Merge, clean, and analyze data	\$10,000		
Write Report	\$10,000		
Total Labor	\$168,000	Grand Total*	\$340,000

*Note that costs for labor, toxicology analysis, and other materials can vary substantially by State and/or organization chosen to conduct the study. This budget example is meant to provide a rough estimate of what a State can expect to pay for a statewide roadside study collecting breath and oral fluid samples.

Table 6. Example Budget for One-Time Statewide Study (Blood)

Labor Cost Item	Estimated Cost	Materials and Other Cost Items	Estimated Cost
Preliminary Planning	\$25,000	Participant Payments (N = 1,000)	\$50,000
Submit to IRB	\$3,000	Lab Fees (N = 1,000)	\$125,000
Coordinate with sites	\$3,000	Training Development Supplies	\$2,000
Train data collectors		Rental Vans for Data Collectors	\$4,000
Manager(s) (1 x 2 teams = 2)	\$1,000	On-Site Storage for Equipment	\$2,000
Safety Officers (1 x 2 teams = 2)	\$1,000	Tablet Programming	\$1,000
Local data collector (5 x 2 teams = 10)	\$5,000	Data Collection Supplies	\$10,000
Collect data		Preliminary Breath Test Devices	\$5,000
Manager(s) (1 x 2 teams = 2)	\$20,000	Travel and lodging	\$50,000
Safety Officers (1 x 2 teams = 2)	\$20,000		
Local data collector (5 x 2 teams = 10)	\$80,000	Total Other Costs	\$249,000
Merge, clean, and analyze data	\$10,000		
Write Report	\$10,000		
Total Labor	\$178,000	Grand Total*	\$427,000

*Note that costs for labor, toxicology analysis, and other materials can vary substantially by State and/or organization chosen to conduct the study. This budget example is meant to provide a rough estimate of what a State can expect to pay for a statewide roadside study collecting breath and blood samples. Costs associated with adding collection of oral fluid samples can be seen in Table 5.

Step 3. Select Drugs of Interest and Join With a Toxicology Laboratory

Step 3A – Select Drugs. A variety of over-the-counter medications, prescription medications, and illegal drugs may be of interest. Talking with law enforcement agencies, prosecutors, and the local toxicology laboratory³ can provide information on which drugs are being seen and detected in the State to help determine if these drugs are of interest to the study’s research questions. NHTSA tests for drugs that are known to have the ability to impair driving-related skills and have a likelihood of being present in drivers.

Toxicology labs generally begin the drug detection process by conducting a series of screening tests. As the term implies, screening is a relatively inexpensive and quick first-level chemical test to determine whether a given drug or group of drugs are likely present in the sample. The cutoff threshold (the minimum drug level at which the screen will return a positive result) for each screen is set to optimize detection while minimizing the number of false positives. Samples that screen positive for one or more drugs then undergo the more extensive (and expensive) confirmation testing using sophisticated laboratory equipment. Figure 1 provides an example of the screening and confirmation results for three different samples.

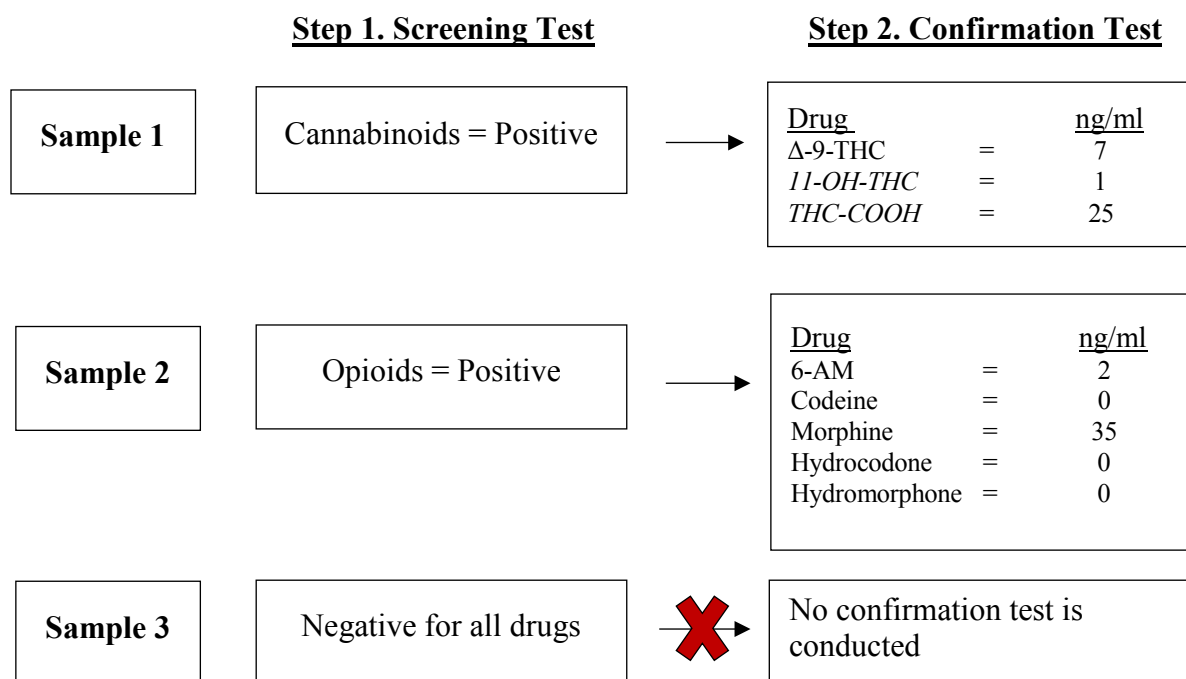


Figure 1. Example of Drug Screening and Confirmation

³ The study can use another lab to conduct the testing, but a local lab can provide an initial indication as to which drugs are prevalent in the area. Note that this will be limited to the drugs they test for as part of their normal activities, and the roadside study may want information on more drugs.

Although specific methods differ, oral fluid and blood samples both require screening and confirmation tests. Without confirmation testing, it is possible a sample will be reported as positive for a drug when the sample is actually negative (false positive), which is why both types of testing are needed. As seen in the example provided earlier (Figure 1), the confirmation test determines exactly which drugs are present and at what level. Sample 1 screened positive for cannabinoids (cannabis), and the confirmation test showed the presence of the main psychoactive drug component (Δ -9-THC) and identified two metabolites (*11-OH-THC* and *THC-COOH*). Sample 2 tested positive for one of the opioid group screens, but it is not possible to know which specific opioid contributed to the positive test without a confirmation test. The confirmation test identified levels of heroin (*6-AM*) and morphine. Sample three screened negative for all drugs and thus, did not undergo confirmation testing.

Costs for toxicology testing can vary substantially. For example, it is relatively inexpensive to test drivers' oral fluid samples for only cannabis compared to testing oral fluid and blood samples for around 80 drugs/metabolites, as has been done in prior NHTSA studies. Toxicology laboratories have a lower cost for screening tests, as these tests are relatively simple in nature. Confirmation testing requires expensive equipment and specially trained staff and is therefore more expensive. Sometimes a lab will offer a combination price for both screening and confirmation testing based on the expected number of samples and an estimate of how many of

The laboratory will want to know the general types/categories/classes of drugs to be included in the study. Descriptions of the categories⁴ of drugs NHTSA has included in past roadside studies are below (also see Couper & Logan, 2004). For some of these substances, and depending on the dose and the person, initial use may be impairing but the person may acclimate to the substance and have little or no impairment with continued use, especially at low doses. *Roadside surveys are to determine prevalence of a substance; not whether a person is impaired by that substance.* Table 7 provides the individual drugs and metabolites NHTSA tested for during Washington State's roadside study.

⁴ Drugs may be categorized and classified in different ways. This classification system shows only one way.

Table 7. Washington State's Drugs Tested and Screening/Confirmation Cutoffs

Drugs by Category	Oral Fluid		Blood	
	Screen (ng/ml)	Confirm (ng/ml)	Screen (ng/ml)	Confirm (ng/ml)
<u>Cannabinoids</u>				
delta-9-tetrahydrocannabinol (Δ -9-THC), <i>11-OH-THC (hydroxy)</i>	4	2	10	1
<i>THC-COOH (carboxy)</i>	0.05	0.02	10	1
<u>Opioids/ Narcotic Analgesics</u>				
6-AM, Codeine, Morphine, Hydrocodone, Hydromorphone, Oxycodone, Oxymorphone	20	10	25	10
Buprenorphine, <i>Norbuprenorphine</i>	5	2	1	1
Fentanyl, <i>Norfentanyl</i>	1	0.50	1	0.5
Meperidine, <i>Normeperidine</i>	50	25	50	10
Methadone, <i>EDDP</i>	50	20	50	10
Naltrexone	40	10	25	10
Propoxyphene, <i>Norpropoxyphene</i>	20	10	20	10
Tramadol, <i>Desmethyltramadol</i>	50	25	50	10
<u>Sedatives</u>				
Benzodiazepines: Alprazolam, Bromazepam, Chlordiazepoxide, Diazepam, Nordiazepam, Oxazepam, Temazepam, Clonazepam, Estazolam, Flunitrazepam, Flurazepam, Lorazepam, Midazolam,	5	1	20	10
Barbiturates: Phenobarbital, Pentobarbital, Secobarbital, Butalbital	50	50	100	100
Carisoprodol, Meprobamate	50	50	500	500
Zolpidem	10	10	10	10
Cyclobenzaprine	25	10	25	10
<u>Stimulants</u>				
Amphetamine/Methamphetamine: MDMA, MDA, MDEA, Methamphetamine, Amphetamine, Phentermine	25	10	20	10
Cocaine: Cocaine, <i>Cocaethylene</i> , <i>Benzoyllecgonine</i> , <i>Norcocaine</i>	20	8	25	10
Methylphenidate	10	10	10	10
<u>Antidepressants</u>				
Antidepressants: Amitriptyline, Nortriptyline, Amoxapine, Dothiepin, Doxepin, <i>Desmethyldoxepin</i> , <i>Imipramine</i> , Desipramine, Protriptyline, Trimipramine, Citalopram, Paroxetine, Venlafaxine, Mianserine,	25	10	25	10
Fluoxetine, <i>Norfluoxetine</i> , Sertraline	50	10	50	10
<u>Over-the-Counter Drugs</u>				
Chlorpheniramine, Diphenhydramine, Doxylamine	25	10	25	10
Dextromethorphan, <i>Dextrorphan</i>	50	20	50	20
<u>Other Drugs</u>				
Synthetic Cannabinoids: AM-1220, AM-2201, AM-2232, CP47497, CP47497-C8, HU-210, JWH-018, JWH-022, JWH-073, JWH-200, JWH-250, UR-144, XLR-11	0.25	0.25	5	1
Ketamine, <i>Norketamine</i> , Phencyclidine	10	10	10	10
Ethyl Alcohol	20 mg/dl	20 mg/dl	20 mg/dl	20 mg/dl

Note: Metabolites are listed in *italics*. Metabolites are a product of the human body breaking down the primary drug to excrete it from the body. Some metabolites remain active and can affect psychomotor skills. Other metabolites are inactive but are an indicator of recent drug consumption.

Alcohol. Alcohol has a well-established impairing effect on driving-related skills. Alcohol works as a central nervous system depressant and affects cognitive, physical, and psychomotor functions that are important for safe driving. Even at BACs below legally proscribed levels, drivers can experience impairment including decreased inhibition and diminished concentration. Consider including alcohol in any roadside study of drugs because of its widespread use, its interaction with other drugs, and how often it is present when several drugs are used.

Cannabinoids. Tetrahydrocannabinol (THC) is a natural cannabinoid and the major psychoactive component of cannabis. THC can have a stimulative, sedative, or hallucinogenic effect depending on the individual consuming the drug. The parent drug delta-9-tetrahydrocannabinol (Δ -9-THC or delta-9-THC) and the active metabolite 11-hydroxy- Δ ⁹-tetrahydrocannabinol (11-OH-THC or hydroxy-THC) are potentially impairing. The drug 11-nor-9-carboxy- Δ 9-tetrahydrocannabinol (11-COOH-THC or carboxy-THC) is a further-metabolized substance and does not have known impairing effects. The 11-COOH-THC metabolite could be an indicator of recent use, but for heavy users the compound can remain in a person's system for several days or even weeks.

Opioids/Narcotic Analgesics. Opioids, or narcotic analgesics, are generally used to treat acute pain. This class of drugs can have negative effects on driving performance due to sedation, respiratory depression, fatigue, lightheadedness, and pupillary constriction. Continued use of these drugs may allow the body to adapt to the effects, which makes the initial use period and times of withdrawal the highest risk for driving impairment; however, any use of these drugs is potentially impairing for drivers.

Sedatives. Sedatives work in different ways to depress/slow down the central nervous system. Several types of drugs including benzodiazepines, barbiturates, muscle relaxants, and sleep aids can be classified as sedatives. Benzodiazepines are prescribed to treat anxiety, seizure disorders, and sleep-related disorders and can cause cognitive and motor function impairments. In addition, benzodiazepines may produce side effects such as weakness, clumsiness, loss of balance, dizziness, and distorted vision. Barbiturates are used to manage anxiety, seizures, and insomnia. Barbiturates can cause sedation and reduced coordination, but these drugs have largely been replaced therapeutically by benzodiazepines. Muscle relaxants are used to treat muscle spasms or muscle spasticity caused by nervous system damage. These drugs may cause drowsiness, ataxia, or blurred vision. Hypnotics are generally prescribed as sleep aids for people who suffer from insomnia. These drugs may cause dizziness or mild to extreme drowsiness.

Stimulants. Stimulants such as amphetamines and cocaine act on the central nervous system and generally increase alertness for short periods of time. Some stimulants may be prescribed to treat attention-deficit hyperactivity disorder (ADHD), or for weight loss.⁵ Side effects of stimulants include dizziness, sleep problems, headaches, and irritability. Their effects on driving performance are not well known.

Antidepressants. Selective serotonin reuptake inhibitors (SSRIs), serotonin, and norepinephrine reuptake inhibitors (SNRIs), tricyclics, monoamine oxidase inhibitors (MAOIs), and noradrenaline and specific serotonergic antidepressants (NASSAs) are commonly prescribed to treat depression, anxiety, personality disorders, and a wide variety of other conditions. During

⁵ Caffeine and nicotine are stimulants that are not a part of most roadside survey toxicology analyses.

the first weeks of use, these drugs can cause dizziness and other side effects. Similar side effects may be experienced when stopping use.

Over-the-Counter Drugs. A variety of drugs can be purchased without prescriptions, and these drugs can be impairing. Over-the-counter drugs of interest often include antihistamines which work to stop allergy symptoms, and cough suppressants that aim to suppress the coughing reflex. These drugs can have sedating effects, although tolerance can develop after use for several days. Dextromethorphan is a synthetic analog of codeine that acts as a depressant. It is prescribed to treat coughs and taken in high doses for recreational use. Third-generation antihistamines such as fexofenadine may not have any impact on driving because they generally do not cause drowsiness.

Other Drugs. Drugs such as synthetic cannabinoids (also known as herbal or liquid incense), may be of interest in specific jurisdictions and can be included if the lab can conduct screening and confirmatory tests. Other drugs of interest include phencyclidine (PCP), which was originally created to serve as an anesthetic, but its severe side effects led to it being disallowed for human use. Ketamine is a drug generally used for anesthesia but can be used for other purposes. When used recreationally, however, PCP and ketamine may cause hallucinations, dizziness, diminished reflexes, and nystagmus (rapid involuntary movements of the eyes). A new drug, α -pyrrolidinopentiophenone (commonly known as “Flakka”) is said to cause bizarre behavior, agitation, paranoia, and delusions of superhuman strength. This particular drug, however, requires a screening test separate from other drug panels and will increase lab testing costs. There may be challenges associated with testing for these types of drugs, and cost implications should be considered.

Step 3B – Select Toxicology Laboratory. The study must include a toxicologist and laboratory capable of guiding the collection of biological samples and analyzing the samples. This is done early in the study to learn what is involved from a cost and planning standpoint. Labs vary in their testing capabilities (including equipment and training of staff), and the analysis needs can vary depending on the research questions.

The State may have its own State-run toxicology laboratory. Private research or clinical labs exist in many States, or samples can be sent out of State. It is important to evaluate a lab’s ability to detect specific drugs of interest, and it is best to use a single lab to ensure protocols are the same over time. Labs can typically test for a “panel” of drugs at one time, and may offer prices that provide a package rate. The lab may be able to provide a discount for a large number of samples. Additional drugs may require separate tests and incur additional charges. Regardless of which lab is chosen, learn their requirements for handling and storing samples after collection, and for shipping samples to them. When talking with a toxicologist about a lab, it is important to ask about its capabilities, costs, and availability of personnel – including these questions:

- Can you conduct screening tests for the drugs of interest? Can you conduct confirmation testing for the drugs of interest?
 - What screening method do you use, and why?
 - What confirmation method do you use, and why?
 - What are your suggested cutoff (threshold) and confirmation levels for the selected drugs? These levels can vary across labs. Ideally, it is best if a lab has low thresholds to be able to detect the presence of a substance at low levels.

- What are your quality control procedures?
- For oral fluid sampling, do you provide the necessary collection devices, or what is needed?
- For blood sampling, how many milliliters of blood is needed for your testing requirements? This is important to know to ensure an adequate amount is obtained.
- What type of blood collection tube is needed? Blood sample tubes (e.g., gray top, red top) are used for different purposes, and some have preservatives to stabilize the sample until it is tested.
- Do the oral fluid or blood samples need to be refrigerated or frozen before and during shipping?
- Do the blood samples need to be centrifuged?
- How long will it take you to analyze the samples?
- How will the results be reported?
- Can you provide examples of how drug test results will be reported and explain what the presentation of results indicates? This is important to have a sense of what you will be getting, and whether it will be understandable to you and your audiences. Toxicological results and lab presentations can be difficult to understand.

Step 4. Develop a Data Collection and Analysis Plan

A thorough data collection and analysis plan is necessary to conduct a sound roadside study. Once the drugs of most interest have been determined, it is important to develop a detailed plan as the foundation for the study. It can be distributed to partners so they can understand the project's objectives, drugs of interest, data collection methodology, and each player's role in the process. The final study protocols will need to be reviewed by an Institutional Review Board as described later in this guide.

A team of experienced people can ensure the study plans are appropriate given the study objectives. While the planning process can be time-consuming, defining the entire study design prior to collecting data will prevent wasting resources collecting information not relevant to the objectives. A person experienced in putting together these types of plans leads with additional inputs from the other experts. Team members can come from State or local agencies, universities, or the private sector. Ideally, some experts to include in the process include the following:

- Researchers with epidemiology experience in sampling frame development and study design
- Researchers with experience in obtaining data from drivers at roadside
- Professionals in obtaining and handling biological specimens such as breath, oral fluid, or blood samples
- Statisticians with experience in sampling design and data analysis involving weighting

- Toxicologists at a forensic laboratory with experience conducting screening tests and confirmation tests for the drugs of interest
- Law enforcement officers with experience working traffic events, coordinating with other agencies, and obtaining approvals from local partners
- Agency, city, or county attorneys to ensure protocols are appropriate and legal for drivers' voluntary and anonymous participation.

The plan includes these topics:

- Objectives
- Drugs of interest
- Sampling plan and site selection approach
- Site recruitment and coordination with local officials
- Data collection protocol, including special conditions, such as public health concerns
- Data collection times
- Site setup
- Driver recruitment
- Eligibility, consent, and survey questions
- Collection and handling of biological samples
- Procedure for handling participants who are suspected of being impaired (for any reason) and for which the study will ensure a ride home
- Data collection equipment.

Step 4A - Develop a Sampling Plan and Select Sites. Developing a sampling plan is important for a roadside study because it allows for the collection of data that represent the statewide driving population or other target populations of interest. Without this, statements about drivers in the target population cannot be made because the sample would not be representative. To maximize representativeness, seek a range of population densities and geographic regions. The basic steps to developing a valid sampling plan are listed below with examples from the roadside study in Washington.

Select a Sampling Frame. A sampling frame is simply a list of characteristics that defines or “frames” the population from which a study plans to sample. For a statewide roadside study, it is important to have a representative sample of all drivers in the State. For a sample to be “representative” it must include participants from all major driver populations across the State. This means it must include drivers from rural, suburban, and urban areas. Other factors such as age, sex, race, vehicle type, day of week, time of day, and roadway type may also be of interest for sampling frame development if the study is focusing on specific subpopulations of drivers. For most statewide studies, however, the sampling frame includes active drivers in the State and stratification based on population density.

Determine Sample Size. As it is impossible to gather data from every driver in the State, a roadside study must rely on drawing a sample of drivers. It is important to determine ahead of time how large of a sample is required to have confidence in the results. A professional statistician will be a benefit. For a one-time measurement of prevalence, the equation below can be used to calculate the sample size needed for a given drug prevalence rate at a specific level of statistical confidence and precision.

$$n = \frac{Z^2 P(1 - P)}{d^2}$$

n = sample size

Z = Z statistic for a level of confidence (e.g., $Z = 1.96$ for 95% confidence)

P = expected drug prevalence (e.g., 15% or 0.15, estimated)

d = precision (e.g., 3% or 0.03 which provides a confidence interval of $\pm 3\%$)

Statistical confidence is a representation of what percentage of the time a study would get the same/similar result if another sample was selected from the same population. Most researchers use 95% as an acceptable level of statistical confidence, which corresponds to a Z value of 1.96. Precision refers to how much variability in the result is acceptable if multiple samples were to be taken. For roadside studies, it is important to be precise, which means a large sample size may be needed depending on how prevalent the drugs of interest are among the sampled driving population. The best way to estimate prevalence is to look at prior research to the extent it is available. If no good prevalence indicator is readily available, examine sources of information such as hospital data. For example, some State trauma registries will have drug use by patients and reports may be available. Law enforcement agencies may have data available regarding drug test results for “driving while intoxicated” arrests. Self-report surveys from other State or Federal agencies may be available where researchers simply asked respondents what drugs they use.

As an example, Washington State’s roadside study found Δ -9-THC⁶ presence to be around 15% for drivers during the baseline measurement period. To have 95% confidence in a study with an expected individual drug prevalence rate of 15% and $\pm 3\%$ precision, a study requires 545 participants as seen here.

$$n = \frac{(1.96)^2 (.15)(1 - .15)}{(.03)^2} = 544.23 \text{ or about } \underline{\underline{545}} \text{ participants}$$

If the expected drug prevalence rate is lower, as it was in Washington for stimulants (6.8% of drivers positive) during Wave 2, a more precise estimate is advisable, and the sample size increases. If the goal is 95% confidence in a study with an expected drug prevalence rate of about 7% and $\pm 1\%$ precision, a sample of 2,501 participants is needed as seen on the following page.

$$n = \frac{(1.96)^2 (.07)(1 - .07)}{(.01)^2} = 2500.88 \text{ or about } \underline{\underline{2,501}} \text{ participants}$$

⁶ Delta-9-tetrahydrocannabinol also spoken as “delta 9” or written as “ Δ -9-THC”, is the active (impairing) component of cannabis.

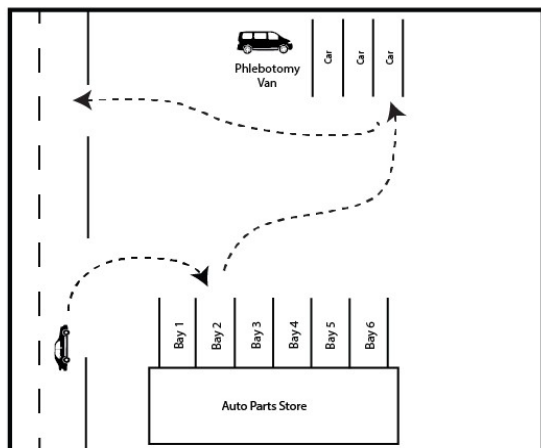
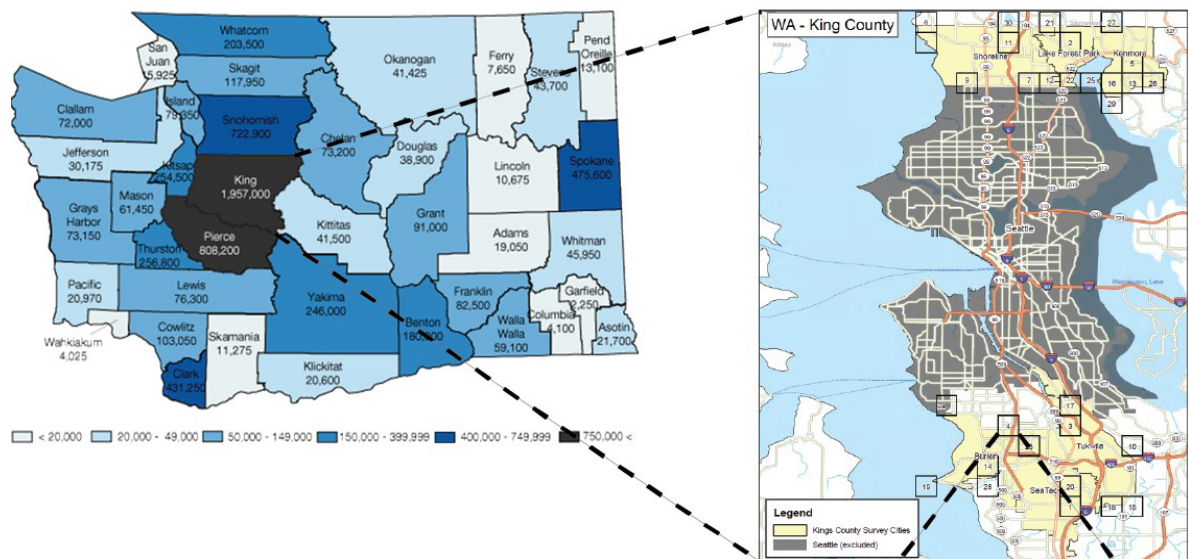
Achieving precise estimates for drugs with low estimated prevalence requires a very large sample. It is recommended that a statistical expert conduct a power analysis taking into consideration the factors that can influence how big a sample needs to be to detect the changes or differences of interest, and then balance those sample size needs with the available budget.

Identify Potential Data Collection Sites. Examining a map of the State with counties' population size is needed. Counties are typically stratified into one of three levels of primary sampling units (PSUs) for a roadside study as follows:

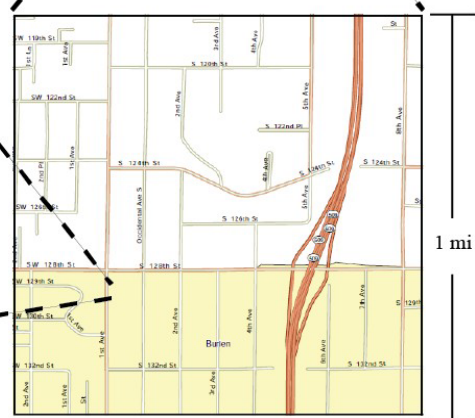
- “A-level” urban counties that are densely populated
- “B-level” suburban counties with semi-major population areas
- “C-level” rural counties that are the least densely populated

The figure on the next page describes the site selection process used in Washington. The researchers reviewed the county population map in Washington and divided the counties into PSU density levels (A, B, or C), and then looked for groups of contiguous and demographically homogeneous counties. Random selection is the most statistically valid and unbiased approach to selecting sampling locations across counties within each PSU category. Traditionally, statewide roadside surveys do not target areas known for impaired driving arrests or near bars. The goal is to learn the prevalence of alcohol and drugs among drivers across the State, not to purposefully aim for “high numbers” of drug positive drivers to make a point, or conversely, to avoid such areas. Inclusion of more counties, or broader areas of coverage, may require partnering with multiple law enforcement agencies, and more travel time between data collection locations. Again, balance the need for the best data possible with the reality of budget constraints. Washington State’s roadside study included one A-level, two B-level, and three C-level counties, which provided coverage of the State both geographically and for population density.

Step 1: 30 square-mile grids were randomly chosen from within selected counties in Washington State



Step 3: Managers sketched layouts of selected locations



Step 2: Managers, with law-enforcement help, identified locations within each grid to conduct the study

Figure 2. Washington Roadside Study Site Selection Flowchart

Once counties or other sampling regions, such as groups of counties, are selected, the next step is to segment each area into subsections for data collection locations (Figure 2, Step 1). In Washington, the research team segmented each selected county into one-mile squares, although smaller or larger squares can be used. Squares with expansive uninhabited areas (e.g., lakes, forests) were removed. The researchers then randomly chose squares for closer examination.

The next step is identifying one roadway segment in each selected square (Figure 2, Step 2). The location needs to provide sufficient viewing distance to allow drivers to see a researcher at roadside and safely slow down to enter the data collection area. Locations for nighttime data collection benefit from overhead lighting from streetlights or night lighting from buildings. There must be off-road parking with space for survey bays (see Figure 3). The intent is to provide both researchers and drivers with a safe space to interact. This roadway review procedure is repeated for all the potential locations to ensure their suitability. It is preferable to have each sampling location in a different square-mile grid area of the county. If staff are unable to identify a suitable sampling location within a square-mile, randomly select among the remaining grids with viable locations within the same county until the sample is complete. The goal in the Washington study, based on its sampling plan, was to collect data from 30 locations across the 6 counties (5 data collection locations in each of the 6 counties).

It is important to select one back-up location for each sampling time slot in case a site becomes unavailable, as may happen with road construction or a crash in the area. These back-up locations should be within the same one square-mile grids as the original locations. As shown in Figure 2, Step 3, it is useful to sketch a layout for each potential site to create a reference guide for project personnel as they arrive. Local officials may also find these of benefit when learning about the project. In some instances, local officials may want to approve specific locations.

Determine Sampling Times. Because it is not practical or cost-effective to conduct data collection 24 hours a day, 7 days a week, study staff must decide when data collection will occur. This must be done carefully and consistently because the timing of sampling can have profound effects on the volume of traffic and drivers who will be at that location. For consistency and to examine trends across years, NHTSA uses the same time frames for its national roadside surveys (Friday daytime was added in 2007), and used these same times for the study in Washington:

- Friday daytime – either 9:30 a.m. to 11:30 a.m. *or* 1:30 p.m. to 3:30 p.m. (alternating)
- Friday nighttime – 10 p.m. to 12 a.m.
- Saturday early morning – 1 a.m. to 3 a.m.
- Saturday nighttime – 10 p.m. to 12 a.m.
- Sunday early morning – 1 a.m. to 3 a.m.

Each sampling period is only 2 hours per location, but there is a substantial amount of time needed for the team to load equipment in the research vehicle, setup and breakdown equipment, and travel to and from each location. For a sense of staff hours needed, expect to cover 40 hours or more of labor for each person involved with data collection over a single weekend. A broader range of days and times will make the sample more representative of all drivers, but costs can increase quickly. Also, conducting data collection is not financially feasible when there is little to no traffic on a road. Because of this, checking traffic counts from the State Department of Transportation will be beneficial. This will allow research teams to be sent to locations where traffic can be expected to be high enough to produce a reasonable number of participants.

Step 4B – Finalize Data Collection Protocol. There must be a detailed data collection protocol, detailing the methodology to recruit participants and request their consent for participation. This plan describes how the researchers will set up the locations, the questionnaire administration process, how biological specimens will be obtained, incentives for drivers, the role of safety/security personnel, and how staff will deal with noticeably impaired drivers. The plan must also ensure compliance with any legal concerns, and ensure privacy of participants.

Location setup. A roadside study involves the setup of multiple data collection bays in a parking lot⁷ or other open area as shown in Figure 3. A research staff member will guide interested drivers to the bays to learn about the study. If a driver chooses to participate, the researcher will provide questionnaire items, a breath test, and provide an oral fluid/blood test. For blood collection, a separate research vehicle may be necessary with a seat for participants to sit while the phlebotomist obtains a blood sample. Each data collection location follows a similar setup.

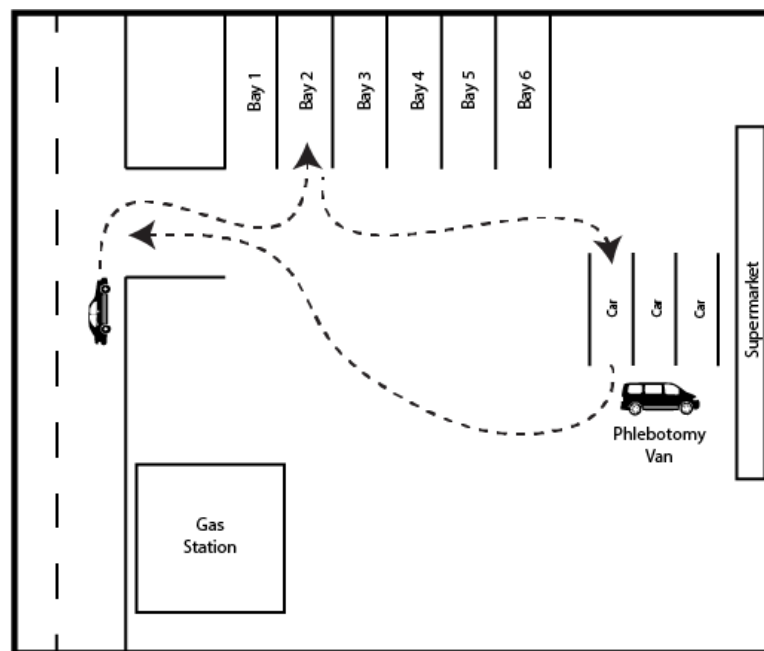


Figure 3. Example of a Bay Setup at a Location

⁷ Ask the owner of the parking lot for permission.

It is also important for the site setup description to include a list of recruiting and safety equipment and how everything is deployed. To get the attention of passing motorists, large 36- to 48-inch orange traffic signs (Figure 4) should be placed before the survey location. It is best to deploy three signs; the first placed well before the data collection bays (several hundred feet or more if possible), the next about halfway to the bays, and the third at the entrance to the bays. To maximize participation, the signs should indicate the survey is voluntary and meets public health requirements, and can include how much is being paid for participation. A large banner (Figure 4) may be useful to let drivers know what the survey is about or who is sponsoring the effort. Figure 5 shows what the setup will look like at night.



Figure 4. Examples of Signs



Figure 5. Example of Nighttime Collection

The following equipment is generally needed at a location when recruiting drivers from live traffic:

- Traffic signs and stands
- Study banners
- Traffic cones
- Traffic wands
- High-visibility safety vests
- High-visibility rain ponchos
- Umbrellas
- CPR masks
- First aid kit
- Sanitizing materials including wipes and a biohazard spill kit

Driver recruitment. The data collection protocol needs to include details on how drivers will be recruited from active roadways and the level of incentive offered. The goal is to get a random sample of drivers out of all those that are passing by. It is important that recruitment not be biased towards recruiting specific types of drivers because they are easier to get to participate or because the researcher thinks they may be more likely to be drug positive. The protocol could include instructions to data collectors such as “Attempt to recruit every fifth driver who passes by” if there are concerns about selection bias and traffic flows can support such procedures.

Having uniformed police officers wave in drivers has become controversial in recent years as some drivers may have felt participation in the study was not voluntary. The current recommendation is to use large traffic signs, in combination with research team members waving traffic wands, to encourage drivers to enter the study site. If the data collection location is near a stop light or stop sign, the team members may be able to guide drivers to the study bays. The signs should clearly indicate the study is voluntary and can mention the amount of incentive. Incentives generally range from \$5 to \$50 per driver depending on how long the data collection takes and if biological samples are being requested. Higher incentives are used when oral fluid and/or blood are being collected. Typically, an incentive has not been needed for drivers to provide a breath test as the action is so quick, and participation rates have been high. Although it may seem like a cost savings, providing a low incentive may impact the participation rate and actually increase costs because more time is required to gather the desired sample size. The incentive should be high enough that many drivers would be willing to participate in the study, but not so high that there can be a perception that drivers are overly pressured. A brief pilot test can help determine the best incentive amount to balance cost with participation rate.

Eligibility and consent. Drivers who want to participate in the study must meet eligibility requirements. The data collection protocol will clearly establish eligibility, how consent will be obtained, how participants will be interviewed, how the collection of the biological specimens will occur, and how privacy of participants will be protected.

Learn more in Appendix A: Consent Examples.

The protocol also provides wording for telling a driver they do not meet the study requirements. Previous roadside studies of passenger vehicle drivers used the following eligibility inclusion/exclusion criteria.

Inclusion

- Must be operating a personal vehicle (e.g., car, pick-up truck, van, SUV, motorcycle).
- Must be at least 18 years old unless the IRB and/or State allows those under the age of 18 to consent to participate without parental approval.
- Must comprehend English or other language for which there is a team member fluent in that language, and consent forms are available. For the National Roadside Surveys, data collection teams must have a member fluent in Spanish, and material written in Spanish. Each State should consider whether other languages are appropriate given its population.

Exclusion

- Drivers of large commercial vehicles, recreational vehicles, and conversion vans are usually ineligible to participate unless they are special populations of interest. A State should consider whether there is a benefit to including moped/scooter riders.
- Severely intoxicated drivers are ineligible as they are unable to provide proper consent. No person can serve as a study participant unless they understand what data is being requested.
- Drivers who sought out the survey to participate (e.g., heard about study through friends or relatives who just participated and want the incentive) are ineligible because such people are not “randomly selected drivers on the roadway.” This has happened several times in National Roadside Surveys, and NHTSA’s protocol includes an initial question of drivers as to whether they heard about the study before entering the research bay.
- A study may want to exclude people who are “at work” in their vehicle, such as delivery drivers, so they are not delayed for their work and because company drug policies while on the job may bias results.

During special circumstances, such as with the COVID-19 public health emergency, additional inclusion/exclusion criteria may be warranted to protect research staff and the driving public. Consult with local public health officials or an infectious disease specialist for strategies to maintain safety while allowing as many people to participate as possible.

Data collectors must fully inform potential participants of the nature of the research, that participation is voluntary and anonymous, and that the participant can stop at any time. Participants must understand the study’s purpose and procedures, the risks and benefits of participating, that participation is voluntary, and that they may skip any part of the study at any time. All participants must provide verbal and/or written informed consent to be included in the study, and are ineligible if unable to provide informed consent.

NHTSA strictly maintains driver anonymity during data collection. In past studies, participants “signed” a consent form, however only an “X” was requested – the participant’s name was never recorded. To do this, a waiver of documented informed consent was obtained during the planning process from the study’s IRB. Even though participants are not asked to sign consent forms, the informed consent process must still occur with researchers receiving a consent verbally from each participant, and for each part of the study (i.e., questionnaire, breath test, oral fluid sample, blood draw). An optional conversion protocol can be used to attempt to further encourage a driver who initially declines to participate in the data collection to change their mind. A

conversion protocol typically involves offering a larger incentive or simply having the site manager better explain the study after a driver initially declines. This method can increase the participation rate of drivers but must be used with care to avoid being considered coercive. The study's IRB must approve this process.

Sequence of Data Collection. The data collection protocol must provide a detailed sequence for collection of observational data, how questionnaires will be administered, how biological specimens will be obtained (including where additional consents are required), and the specific materials to be used. The protocol covers the following:

- How participant identification numbers will be assigned
- How observed demographic information (e.g., age range, sex, race) and other information (e.g., vehicle type, seat belt use) will be recorded
- The sequence of data collection activities with consent requested as appropriate. This sequence has worked well for NHTSA data collections as it allows repour to build between data collector and participant before the more sensitive requests are asked.
 - Questionnaires
 - Breath alcohol test
 - Oral fluid
 - Blood
- Whether BAC readings will be hidden (masked) from data collectors
- When and how an impaired driver protocol⁸ will be enacted.

Learn more in Appendix B: Impaired Driver Protocol.

A State should consider which demographic data is important, especially considering difficulties associated with determining some variables (e.g., age, race) via observation, or the need to ask for self-reported information. NHTSA has developed the sequence of asking for a breath test first followed by an oral fluid sample, and then a blood sample. Questionnaires can be inserted in the process as needed to allow the driver to become familiar with the data collector or to fill time during oral fluid collection.

Equipment for Data Collection. Costs for supplies could vary substantially depending on the instruments used. The basic data collection equipment includes the following:

- Computer tablets
- Paper data collection materials
- Preliminary breath test (PBT) devices
- Oral fluid collection devices
- Phlebotomy kits for blood sample
- Cold storage for oral fluid or blood samples

⁸ NHTSA uses a .05 BAC as its threshold for enacting its impaired driver protocol – allowing more caution than the .08 BAC threshold for a per se driving offense charge in most States (Note: Utah has a .05 BAC per se law).

Computer tablets can be very useful for recording observational data, administering surveys, and scanning barcodes on oral fluid collection materials or blood tubes. The tablets can prompt data collectors to follow consent procedures and to make sure all critical data items are entered. The system can link all the data for a given participant and easily offload the data to the study database for analysis. Such systems, however, require programming capabilities and an understanding of how to configure survey branching (e.g., skipping some items based on a given response to another item), as appropriate. Tablets also require hard-body cases to protect them from damage due to drops or if it begins to rain or snow. Even if staff use a computer tablet, they will still need paper backups of all data collection materials because tablet systems can fail.

A PBT is essential for any roadside study as it allows for the measurement of blood alcohol concentration without the need for a blood sample. BrAC is measured when the subject blows directly and forcefully into the device. For research purposes, it is highly recommended that the PBT is “masked” so neither the researcher nor the participant can see the result during data collection. The masking can be done through software that prevents the result from being displayed or simply by taping a cover over the screen display. The site manager will later download all participants’ BrAC results. This approach ensures participants’ BrAC results are completely anonymous to the survey team.

A phlebotomy kit includes everything to collect blood samples on site. A toolbox or other easily carried storage system can keep supplies together (Figure 6). The contents include the following:

- Grey-top blood tubes
- Gloves
- Tourniquets
- Antiseptic wipes
- Band-Aids
- Sterile gauze pads
- Butterfly needles
- Straight needles
- Vacutainer
- Eye wash
- Biohazard spill kit
- Headlamp
- Hand sanitizer
- Disinfecting wipes
- Absorbent pads
- CPR mask
- Sharps container
- Labels for subject number



Figure 6. Phlebotomy Kit

A number of oral fluid collection devices are available, but they work in the same basic manner. The participant places the fluid collection pad in the mouth (usually in the cheek or under the tongue) and waits while the pad absorbs saliva. The process takes approximately three to five minutes. Some devices have an indicator that changes color when enough fluid has been collected. Once the participant is finished, the pad is sealed in a tube containing a stabilizing buffer solution. These samples must be sent to a toxicology lab for screening and confirmatory testing to determine the presence of a drug. These types of oral fluid test devices are different than “on-site” drug testing devices sometimes used by law enforcement, which are designed to give an immediate indication of the presence of a drug or class of drugs. On-site devices do not provide secondary confirmation testing and would not generally be used for a roadside study, especially due to the desire to keep results anonymous.

The biological samples need to be kept in cool storage while the team is still out in the field. This can be accomplished with use of a small cooler and ice packs (Figure 7). Once data collection is finished for the session, the samples are moved to a study refrigerator for cold storage until shipment to the laboratory. The study’s toxicologist can provide specific storage and shipping information.



Figure 7. Storage Cooler

Step 4C - Institutional Review Board (IRB) Approval. All government-funded research studies involving human subjects must be reviewed and approved by an IRB complying with rules set by the U. S. Department of Health and Human Services.⁹ This is to ensure ethical procedures when dealing with human subjects. All consent forms and study protocols must be approved before data collection can begin. Given the complexity of a roadside study, the IRB review process may take several weeks or even months. The organization hired to conduct the study may have its own IRB (e.g., university IRB), or independent IRBs can be used for a fee. Costs will vary from no charge for in-house review at some organizations up to several thousand dollars for an independent IRB depending on the complexity of the protocol. In addition to IRB approval, study organizers must take all necessary steps to ensure the protocol complies with applicable Federal, State, and local laws and regulations.

Step 5. Staff and Train Data Collection Teams

Step 5A – Staff the Team. Running an effective roadside study typically requires a lead field data collection manager, multiple on-site data collection managers, data collectors, and research assistants. It is essential all personnel can perform their job duties and follow the protocol for data collection consistently from site-to-site. If the study is collecting blood, it will need one or more certified/licensed phlebotomists (or qualified nurses, EMTs, etc.) per data collection team. Trained project personnel can collect oral fluid or conduct breath tests without a license or certification, but it is essential that they fully understand and comply with the procedures established by the device or collection kit manufacturer. Protocols for collection, storage, and transport of biological samples, particularly blood samples, should be developed in close coordination with medical professionals to ensure integrity of samples and compliance with health and safety laws. All staff must complete, at a minimum, an online human subjects training program.

The number of team members needed at a given data collection location can vary depending on the anticipated flow rates of drivers and what types of samples will be collected. It does not make

⁹ Web page and portal at www.hhs.gov/ohrp/about-ohrp/index.html

sense to have a team capable of processing multiple participants simultaneously when very few participants are expected based on traffic counts. On the other hand, the study could need multiple groups of collectors working simultaneously at a high flow location to avoid losing any potential participants because wait times are too long. As an example, the 2013-2014 National Roadside Study teams consisted of one on-site data collection manager, one phlebotomist, and six to eight data collectors. The number of teams will depend on whether data will be collected simultaneously at multiple sites, or whether a single team will go from site-to-site each week.

The primary responsibilities for each job title are provided below. Some job responsibilities could be combined into a single position.

Lead Field Data Collection Manager. The lead field data collection manager is in charge of all things related to the field data collection efforts. This position oversees and facilitates the data collection activities including supervising the hiring and training of all team members, scheduling of all field data collection activities, management and control of all equipment, data transmission, and quality control. The position also involves the purchasing of supplies, as well as coordinating with local agencies for data collection site location selection and setup. This person may attend some data collections but is not needed on-site.

On-Site Data Collection Manager. On-site data collection managers are the leaders in the field for each team during the data collection activities. Their primary responsibility is to oversee the data collectors and make sure the study protocols are followed. On-site data collection managers attend all training sessions and assist with the coaching of data collectors who need additional training on equipment or the protocols. The managers act as a data collector as needed.

On-site data collection managers must travel to sites and individual locations prior to data collection to coordinate with local law enforcement and select the locations. The managers will then sketch maps of each location and outline entrances and exits, bays, and data collector positions to facilitate setup when teams arrive to conduct the data collection. In general, the on-site manager is “in charge” of all activities at a specific data collection event. During data collection, the on-site manager ensures that everyone is wearing a high-visibility safety vest (see Figure 8) and following other safety guidelines (e.g., wearing appropriate medical exam gloves and changing them for every participant). This person is continuously monitoring all aspects of data collection to ensure everything is moving smoothly. The on-site manager is responsible for making sure the location is cleaned up and that all materials are re-stocked. Importantly, the on-site manager must make sure all samples are sent to the laboratory.



Figure 8. Data Collector in High-Visibility Vest

Data Collectors. The role of the data collector is to interact face-to-face with drivers including the following:

- Guiding drivers into the data collection location
- Recording initial observations
- Obtaining informed consent from drivers
- Conducting face-to-face interviews/questionnaires
- Obtaining breath samples
- Obtaining oral fluid samples
- Requesting blood samples (if collected)
- Giving the subjects the study incentives (cash, gift cards, coupons, etc.)

Each data collector is responsible for setting up a data collection bay and making sure materials are quickly accessible. After data collection, data collectors break down their bays and re-pack supplies quickly to travel to the next location with the team.

Research Assistants. Research assistants arrange travel logistics, including flights, lodging, and vehicle rentals. Assistants may also manage supplies, including restocking/packaging bags, checking batteries to keep equipment running, and calibrating PBTs. This position can also conduct data entry.

Safety Officers. The primary responsibility of the safety officer is to observe the data collection and provide safety for both survey participants and the research team, including the following:

- Working with the data collectors to identify a safe sampling location
- Providing security during data collection
- Remaining within sight and sound of data collectors during data collection and watches for any sign of distress. For example, data collectors in the National Roadside Surveys and Washington study were instructed to turn their research cap backwards if they felt uncomfortable and needed someone to intervene.
- If necessary, assisting with implementing the impaired driver protocol.

Safety officers could be local on-duty or off-duty officers, from a private security agency, or retired law enforcement officers paid by the study. Study managers should check with local agencies at each site to determine their preference for the type of safety personnel. If local authorities require on-duty officers to serve as the safety personnel, it is best if they are in unmarked vehicles, and are in plain clothes to minimize the impression to drivers the data collection is an official law enforcement activity. Similarly, to avoid the appearance of law enforcement coercion, officers should not use their vehicles' lights or sirens. It is critical that safety personnel are sufficiently close to data collection to observe interactions but are far enough away to avoid any sense of "hovering" or coercing participation. A roadside study should not appear to be a law enforcement activity. Study protocols for safety officers should be carefully developed in coordination with both law enforcement and legal experts. Any participating law enforcement agencies must agree the data collection event is for traffic safety research and is not a strategy to arrest potentially impaired drivers.

Only one safety officer is generally needed per data collection location. If several data collection locations are operating simultaneously in the same area, multiple safety officers will be needed. A two-hour data collection period usually requires at least four hours of safety officer labor, as this covers setup and breakdown time. More time may be needed to help the on-site data collection manager choose safe locations for sampling. Also, if using law enforcement officers, some departments have minimum shift length and other requirements (e.g., cannot participate in non-safety related activities). Agencies will also have a minimum hourly rate for officers assigned to a traffic-related detail. If needed, the study can pay a higher hourly rate to make participation more attractive. Some agencies require that time be billed through them while others prefer off-duty payments be made directly to the officer.

It is important to have a safety officer protocol available for review by the agency and officers so they understand the job requirements. Because this is a research study, officers may need to go through human subjects training approved by the Department of Health and Human Services. Such training is required for anyone participating in a study that involves direct interaction with human participants to make sure they understand ethical considerations.

Learn more in Appendix C: Safety Officer Responsibilities.

Phlebotomists. Phlebotomists or other qualified medical staff are only needed if blood samples are collected. Phlebotomists travel with the team to set-up the phlebotomy area at each location, conduct the blood draws, and pack the biological samples for shipment to the lab. The phlebotomists, or otherwise qualified medical staff, follow all applicable health and safety rules and regulations and should be properly licensed by the applicable State boards. When not handling a blood draw, a phlebotomist may serve as a data collector.

If there are multiple phlebotomists, a lead phlebotomist will oversee all aspects of blood sample collection including the development and monitoring of procedures for phlebotomists in the field. The lead phlebotomist will be involved with training, monitoring, and reporting on the proficiency of the phlebotomy staff in performing field blood draws. The lead phlebotomist will also be responsible for packing supplies and keeping stock up-to-date.

Step 5B – Train the Team. Given the complexities of the data collection activities, it is critical all teams are fully proficient before the first participant is processed. Each team member must be thoroughly trained in the protocol, and demonstrate proficiency in participant recruitment and data collection. Human Subjects training can either be online or an in-person activity, but

managers must verify all staff working with or near potential participants have completed the training.

Plan to have an additional in-person training session to cover the entire protocol from start to finish, including practicing packing/unpacking equipment, setting up in a parking lot (e.g., cones, traffic signs), working with tablets or paper forms, using PBTs, and following safety procedures. Once managers are satisfied that each team member understands their role and job responsibilities, it is necessary to conduct a full mock-up practice session with simulated participants. This portion of training covers all aspects of data collection from participant recruitment to data offload. Managers also cover common problems, including how to handle impaired drivers. It is important to have all activities continue in line with the data collection plan.

If blood is being collected, phlebotomists should attend a specialized phlebotomy training session in addition to the mock surveys to understand their role in the project and to practice setting up the phlebotomy van/stations under different circumstances. If no van is being used, the phlebotomists practice taking samples from drivers seated in a vehicle and under varying lighting conditions. If blood is to be drawn at night from participants seated in cars, adequate portable lighting and an associated power source must be included in the study's equipment. Finally, all team members are trained in the safe collection and handling of biological samples to ensure all applicable laws and regulations are followed.

Learn more in Appendix D: Data Collector Responsibilities.

Step 6. Recruit Sites and Coordinate With Local Officials

It is important to contact local authorities to ensure the study has permission to conduct the roadside sampling in each jurisdiction. Most locales supported prior NHTSA studies once it was explained why the study was needed and the procedures were clearly described to them. Local officials likely will want to discuss details of the data collection plans, how local law enforcement will be involved, and whether any public pushback can be expected. They will also be interested in the safety of the public and the research team given that drivers are being recruited from active roadways. Some locales may have ordinances limiting contact with drivers, and the study may need special permission to recruit participants. Staff may have to wear identification badges indicating they have approval to be at a location.

Step 6A – Initial contact. Having the detailed data collection plan in hand is important to show the local authorities how the research protocol will be conducted. While every situation is different, some general guidelines for contacting local sites are:

- If available, consider using the State's Law Enforcement Liaisons through the State Highway Safety Office to contact local law enforcement first.
 - Some law enforcement agencies have participated in previous highway safety campaigns, or even a National Roadside Survey, and may support the project. Provide the agency information on why the study is important, their role, compensation, and the benefit to the State. Include a set of questions and answers that can put them immediately at ease about participating.
 - The main liaison will likely be the officer in charge of the traffic unit, or in charge of off-duty officer assignments. However, it is usually necessary to obtain

approval from police management (e.g., chief, sheriff) before the project can begin.

- State Highway patrol agencies generally support traffic safety research. It is beneficial to notify these agencies, especially if data collection occurs in their jurisdiction.
- In some cases, a local law enforcement agency may not have personnel resources to support the effort. Be prepared to recruit another law enforcement agency that also has jurisdiction or, be prepared to choose a substitute site.
- Contact other local officials, such as the mayor's office or city council, prior to data collection. Although approvals from these types of offices may not be necessary, depending on applicable State and local law and regulations, it can be beneficial to alert them ahead of time to avoid potential problems, especially if they hear of the study from other sources.

Step 6B - Alerting media outlets. Roadside surveys can attract attention from local media outlets which means it may be advisable to alert them of the study plans. The research team can do mock "walk-throughs" if reporters are interested in experiencing study procedures firsthand. The walkthrough covers the entire process from recruiting drivers to collecting oral fluid or blood. Informing the media can improve cooperation rates because the public is aware of the activities and will help avoid negative press or complaints from the public. Washington State filmed a mock data collection event and had the video available for reporters and others on a website. *Reporters should not be allowed to film during an actual data collection period because it could violate the anonymity of the participants.*

Step 7. Collect and Analyze Data

Step 7A – Implement the Data Collection Protocol. Once the research team has completed the training and demonstrated proficiency, it is time to collect data. Teams adhere strictly to the study schedule and protocol. Any changes in data collection sites or times will be noted and assessed by the manager because deviations from the protocol can greatly affect the results and overall validity of the study.

Any issues with blood storage or shipping must be fully documented, including events and times, in case the laboratory notes problems with the samples. Continuous and careful monitoring is necessary to identify the causes of any problems so the situation can be rectified before spending funds on the collection and analysis of bad samples. All biological specimens are regarded as hazardous and need to be handled in accordance with applicable laws and regulations to ensure safety for all involved in the study. Team members must wear disposable gloves when handling biological specimens. The survey manager must count the number of samples being shipped and check each day/night that all samples are accounted for and that the associated questionnaire, breath test, and observational data are in place. The survey manager will ensure all data are offloaded from the PBTs and tablets (if used). If paper forms were used, it is beneficial to enter the data as soon as possible to make sure no information is lost, and while data collectors are still available to clarify any issues with data input.

When data collection is finished at a location, the team will need to clean up the area and leave it in good order. The team then proceeds to the next location if more than one location is scheduled in a shift. After each shift, the team members will check all supplies and pack for the next data collection. All tablets and PBTs need to be charged or have fresh batteries installed to make sure they have enough power. All traffic signs and other equipment need to be packed in labeled storage containers.

Step 7B – Manage and Analyze the Data. Roadside studies require substantial coordination and quality control in order to link and manage the data. This is especially true when the study will merge toxicology data with observational information, breath test data, and survey results. In addition to making sure the data are of good quality, the data analysis experts need to determine the best approach for analyzing the data given the study’s specific objectives.

Data Cleaning. Before any analysis takes place, the data must be cleaned to identify if there is missing data or gross errors, and to develop a strategy for dealing with outlier data points. The cleaning is performed by a statistical analyst with good understanding of the research design and experience with the range of reasonable alcohol and drug concentration values based on the types of specimens collected and toxicology tests conducted. At a minimum, the data cleaning involves a review of counts of drivers processed at each site, participation rates, demographic data, drug positive/negative ratios, and drug concentration values (if quantified). Simple tables or plots of data can be used to determine if the data fall into expected ranges. Any issues need to be remedied with the toxicology laboratory or data collectors before the data can be analyzed. Some data may need to be omitted, or special notes made, to ensure the analysis is appropriate for addressing the issues.

Define the Analysis Approach. The specific analysis approach will depend on the nature of the study and associated research questions, and is included as part of the planning process for the study. A one-time study that is focused on only drug prevalence among drivers may not need any inferential statistics. If the State wants to dive further into the data, or if the study collected multiple waves of data, more advanced statistical techniques are warranted. For example, a State may want to determine if there are statistically significant differences among response groups, or differences across waves of data collection. The following sections provide guidance on statistical issues that may be encountered. Examples from the roadside study in Washington (Ramirez et al., 2016) are provided.

Weighting of Data. A study interested in being able to make statements about the statewide prevalence of drugged driving will likely need to apply statistical weights to re-balance the data to be representative of the entire population of drivers in the State. Given the nature of roadside sampling where drivers are volunteering on active roadways, it is unlikely the sample obtained will perfectly match the distribution of driver characteristics in the State. Additionally, the number of drivers interviewed will likely not be in proportion to the differential population and traffic densities of the PSUs due to limiting factors such as number of survey staff and the two-hour time window in which the session took place. These factors generally produce a similar number of participants per data collection session regardless of an area’s traffic density. Therefore, the data must be weighted to adjust the estimates for over- or under-sampled populations to provide a better estimate of the statewide prevalence of alcohol- and drug-positive driving.

There are several approaches to weighting with each having benefits and limitations. The recommended method for a roadside study of statewide drugged driving prevalence is to apply weights based on the driver population proportion for the State in each sampling region. That is, weighting should reflect the relative size of the driving population by region of the State. While this approach is simpler than what may be done for sophisticated sampling frame approaches for other types of data collection efforts, it produces stable estimates by preventing under-sampled populations from over-contributing to the statewide prevalence estimates. This is because other sampling frame probabilities only work under idealized assumptions that can rarely be met with this type of research, and have a high probability of producing an extrapolated population estimate that is vulnerable to serious bias. For these reasons, conventional weighting methods used in other types of research are not recommended. For this type of study, weighting focuses more on driver population representativeness than on sampling frame methods.

The statistician can use census data, driver license counts, and other types of data to estimate the driving population within each region across the State. This approach assumes drivers participating in the study at each site originated from within that particular region. A separate weight is applied to each region to represent the estimated distribution of the drivers in the State. The roadside study in Washington selected six counties to represent the State. As shown in Table 8, that study calculated the expected percentage of drivers contributed by each county as if each represented the entire group/region from which it was chosen. For example, based on an index created for the study using labor force, population, and crash data, the King County sites were estimated to represent approximately 31.06% of the State's driving population. If the actual number/proportion of drivers sampled in each county is different than the expected values, weighting should be applied to provide a better estimate of prevalence for the State.

Table 8. Washington State's Drivers in Each PS

County	% of State Driver Population
King	31.06%
Snohomish	17.84%
Spokane	12.32%
Yakima	13.29%
Whatcom	10.91%
Kitsap	14.59%

For example, during Wave 1 in Washington, only 13.00% of the daytime drivers sampled were in King County which means the study under-sampled there during the day relative to the expected value of 31.06% of drivers. Dividing the expected percentage by the actual sampled percentage provided the case weight ($31.06/13.00 = 2.39$) for any daytime analyses. This means each King County driver's data counted 2.39 times in the weighted daytime analyses. The same process was applied to the other sampling PSUs with some having case weights below 1.00 and others above 1.00 depending on how many samples were collected in each region relative to the expected number based on the driver population estimates. Weighting such as this can have a significant impact on the final statewide prevalence estimates.

Data Analysis. Inferential analyses using chi-square statistics for one-way and two-way cross-tabulations, or simple comparisons of confidence intervals, can be used to compare groups of interest or to determine whether there were any statistically significant changes over time. If there are multiple waves of data, the results could be presented in the same way as those in Table 9 for THC in Washington (adapted from Ramirez et al., 2016). Confidence intervals must be calculated to let the reader know the upper and lower limits within which the true population prevalence proportion likely lies. Wide confidence intervals indicate more uncertainty while smaller confidence intervals indicate greater precision for an estimate. Larger sample sizes will result in smaller confidence intervals and more stable estimates of drugged driving prevalence.

Table 9. Washington State's THC-Positive Drivers by Wave

Wave 1					Wave 2			
	<i>N</i>	% THC- positive	<i>N</i> THC- positive	95% CI	<i>N</i>	% THC- positive	<i>N</i> THC- positive	95% CI
Daytime	271	7.8	23	[5.8,	177	18.4*	34	[12.4,
Nighttime	637	17.5	109	[14.0,	495	19.8	93	[16.5,

In this table, *N*s are unweighted; percentages are weighted. THC-positive includes results from THC and hydroxy-THC.

*Significantly different from Wave 1 ($p < .05$).

Drug prevalence can also be stratified by demographics (e.g., gender, age, race, ethnicity), environmental variables (e.g., time of day), and poly drug use as shown in Table 10 (adapted from Ramirez et al., 2016). While more sophisticated analyses could be performed to answer other research questions, the prevalence results can generally be presented in this easy-to-understand format.

Table 10. Washington State's Drivers THC-Positive by Drug Category and Time

Drug Category	Daytime			Nighttime		
	%	N	95% CI	%	N	95% CI
Wave 1						
THC-positive	7.8	23	[5.8, 10.4]	17.5	109	[14.0, 21.7]
<i>THC-positive only</i>	4.6	11	[3.5, 6.0]	10.5	69	[7.4, 14.6]
<i>THC-positive plus any other drug</i>	3.2	12	[1.3, 8.0]	7.0	40	[4.6, 10.7]
Illegal only	2.2	8	[0.7, 6.6]	2.5	14	[1.5, 4.3]
Medications only	13.1	38	[10.3, 16.4]	17.4	102	[13.1, 22.6]
Illegal and medications	0.0	0	0	0.5	1	[0.0, 3.6]
Total drug-positive	23.0	69	[16.8, 30.8]	37.9	226	[31.7, 44.6]
Total drug-negative	77.0	202	[69.2, 83.2]	62.1	411	[55.4, 68.3]
Wave 2						
THC-positive	18.4*	34	[12.4, 26.4]	19.7	93	[16.5, 23.5]
<i>THC-positive only</i>	13.3*	25	[9.6, 18.1]	13.0	59	[9.9, 16.9]
<i>THC-positive plus any other drug</i>	5.1	9	[2.0, 12.5]	6.7	34	[4.6, 9.8]
Illegal only	1.9	3	[0.9, 3.9]	2.1	9	[1.1, 3.9]
Medications only	11.2	20	[8.5, 14.7]	17.6	93	[14.0, 21.9]
Illegal and medications	1.0	1	[0.2, 5.2]	0.4	1	[0.0, 2.5]
Total drug-positive	32.4	58	[27.7, 37.5]	39.8	196	[35.7, 44.1]
Total drug-negative	67.6	119	[62.5, 72.3]	60.2	299	[56.0, 64.3]
Wave 3						
THC-positive	18.9*	35	[11.9, 28.8]	22.2	114	[17.8, 27.5]
<i>THC-positive only</i>	10.4*	23	[7.8, 13.7]	13.3	69	[9.0, 19.1]
<i>THC-positive plus any other drug</i>	8.6	12	[3.5, 19.5]	8.9	45	[4.9, 15.8]
Illegal only	0.0	0	0	0.2	2	[0.0, 0.8]
Medications only	13.6	37	[6.6, 26.0]	11.6	69	[9.0, 14.9]
Illegal and medications	0.0	0	0	1.2	5	[0.3, 5.3]
Total drug-positive	32.6	72	[23.2, 43.6]	35.2	190	[30.2, 40.6]
Total drug-negative	67.4	142	[56.4, 76.8]	64.8	406	[59.4, 69.8]

In this table, Ns are unweighted; percentages are weighted. Column percentages may not total to 100 percent due to rounding. THC-positive includes results from THC and hydroxy-THC. *Significantly different from Wave 1 ($p < .05$).

Step 8. Report Results

The final product of the study is typically a formal report that includes, at a minimum, an introduction describing why the study was conducted, an objectives section, a methods section, a results section, and a discussion. Each of these sections includes sufficient detail that someone reading the report can fully understand what was done and be able to replicate the methodology. The report must be clearly written to avoid ambiguities or misinterpretations of the findings. An executive summary may be useful for disseminating findings to those who do not want to review the detailed report.

Introduction and Background. A good report will include a brief introduction and background section that provides information on similar prior studies, the motivations for the current study, and how the information collected by the study will be used. This section of the report provides details on how the study was different from, or the same as, prior research. The general goal is to provide enough information that the reader will have realistic expectations for what is to come in the methodology and results sections.

Objectives. A brief objectives section clearly lays out the study goal and any specific objectives, hypotheses, or research questions that the study attempted to address. The primary objectives will have been defined early in the research project development phase, but other secondary objectives or research questions may have emerged that could be explored using the data. While specific hypotheses can be laid out here, often the objectives section is more of a statement of purpose for the research when a study is exploratory in nature. It is beneficial to use action verbs for defining objectives, such as “To conduct a statewide prevalence study of drugged driving” or “To examine how cannabis positive driving changes over time after legalization.” No directionality or expectations of results are implied with these types of general objectives statements. Research hypotheses, on the other hand, have a specific predictive aspect to them such as “Daytime cannabis use will increase after legalization” that the study results may or may not support. In any case, this section needs to clearly demonstrate what the study set out to explore.

Methods. This section lets the reader know how the data were collected and from whom. Because the study methodology can greatly influence the results, this section must be detailed. Much of the information will come from the data collection protocols and IRB submission materials. The section includes details on the study participants, study design, materials used, drugs tested, drug screening/confirmation approach, sampling days and times, site selection, data collection teams, and exact procedures used to recruit participants and gather data. Data collection forms and additional information on materials belong in appendices.

Results. The analyst must check the results for errors before they are published. For a statewide drug prevalence study, all results should be expressed as a percentage of drivers at the times and places of the measurement who had a particular drug in their system. Describe the specific analysis approach used, and include both the weighted and unweighted results with confidence intervals. If multiple waves of data were collected, the report will discuss any changes observed over time, and the statistical significance of the changes. Results should be displayed even if no statistically significant differences or changes were found.

Any issues with the data need to be described to allow the reader to judge the quality of the data and the findings. Only results related to the main study objectives and research questions should

be included to not overwhelm the reader. Ancillary findings can be included in an appendix. The results section includes the study's findings, not interpretation.

Discussion. This final section succinctly summarizes the results and offers potential explanations for the findings. The discussion focuses solely on measures of drug prevalence, how prevalence was different by the factors of interest (e.g., age, sex, time of day), and if there were waves of data collection, any changes over time. It is always the author's prerogative to interpret the findings, and it is beneficial to also discuss any alternative interpretations.

This section includes a description of any study limitations or problems encountered that may have affected the results. For example, if the participation rate was particularly low in some areas of the State, the discussion provides any information as to why it was low, and how the results may, or may not, have been impacted.

Discussion of driver impairment must be made with extreme caution as presence of a drug does not necessarily equate to impairment from it.

Roadside survey results do not support discussions of crash risk.

The authors may want to close the document with recommendations for specific future research. Such recommendations can provide guidance to funding agencies that may be interested in the impacts of drug use on driving or other aspects of public health.

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Appendix A: Consent Examples

The following examples are meant only as samples and must be adapted for specific circumstances and local requirements. These are not meant to be used without changes.

Driver Questionnaire Verbal Consent Script (Read aloud)

“We are conducting an anonymous driver survey. You are being asked to VOLUNTARILY PARTICIPATE in a research study designed to better understand what medications and other drugs drivers may be using. The survey and breath test take just a few minutes and you will be paid \$5 upon completion of both. There is no cost to you. You may skip any question or stop participation at any time. The survey is completely anonymous as none of your responses will be directly linked to you in any way. You will complete the survey on a tablet computer with my assistance if you need it. This part takes about 5 minutes. If you agree to continue now, you will read more information about the study on this tablet and then you can decide, if you want, to take the survey. May we continue?”

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Tablet Questionnaire Consent Language (presented on tablet)

By proceeding with this survey, you are consenting to allow your responses to be included in the research effort that is examining medication and other drug use among drivers. Survey questions ask about your background, where you are driving to and from, and opinions about driver safety. You will then be asked to give a breath sample and may be asked to give a small blood sample. You must be 18 years or older to take part in this study. All results of the study will be reported at the group level and your responses to this survey will not be linked to you in any way. We do not expect any direct benefit to you, but you may help people and save lives in the future. We will give you a copy of information about this study with contact information for study staff. Do you have any questions right now that I can answer?

By pressing “Continue” below, you agree to participate.

Breath Sample Verbal Consent – Masked Results (Read aloud)

“Now I’d like to get a sample of your breath. The results are put into the study database without any link to your identity. Our device does not display any readings that I can see, so there is no risk to you (Show PBT to subject). This will take just a few seconds.

Do you have any questions right now that I can answer?

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Are you willing to participate in this part of the study?”

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Breath Sample Verbal Consent – Unmasked Results (Read aloud)

“Now I’d like to get a sample of your breath. The results are put into the study database without any link to your identity. There is no risk to you. This will take just a few seconds.

Do you have any questions right now that I can answer?

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Are you willing to participate in this part of the study?”

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Paper Consent Information Sheet

Purpose:

The purpose of this study is to identify factors contributing to safe and unsafe driving. Volunteers are being asked to take part as anonymous participants.

Procedures:

This study has four parts.

1. Taking a short survey
2. Giving a breath sample
3. Giving an oral fluid sample
4. Giving a blood sample (about 10 mL, or 2 teaspoons)

Risks/benefits:

There is no direct benefit to those who take part in this study. It is hoped that others will benefit from knowledge gained. Because data are anonymous, there is no expected risk to participants.

For those providing a blood sample, risks are considered minimal. This may include dizziness, nausea, fainting (with or without injury from falling), and soreness or bruising at the site of the blood draw.

Confidentiality:

All results of the study will be reported at the group level and survey responses will not be linked to participants in any way. Leftover blood may be stored for up to 2 years, then destroyed. No genetic testing will be done.

Costs/compensation:

There is no cost to you for taking part. Participants are paid \$5 for a breath sample, \$10 for an oral fluid sample, and \$50 for a blood sample.

Voluntary Participation:

Your participation in this study is completely voluntary and you may withdraw at any time. If you withdraw before the sample collections, however, you will not receive payment.

Contact Information:

If you have any questions about the study, you may call the study's Principal Investigator, XXXXX, at (XXX) XXX-XXXX. This study has been reviewed by XXXXXX IRB, which is a committee to help ensure that your rights and welfare are protected. If you would like to contact them about your rights as a research participant, their email address is XXXX@XXXXX.com and the toll-free number is XXX-XXX-XXXX. The study number is XXXXX.

Participant Statement for Blood Draw

If you qualify and agree to provide the blood sample, please check below.

I certify that I am at least 18 years old. I am not taking any blood thinners and have not been diagnosed with any blood conditions such as hemophilia.

I acknowledge that the procedure has been explained to me and that I have had the opportunity to discuss the blood draw procedure with the certified phlebotomist (or nurse or EMT). I understand all blood results are anonymous. I further understand that my participation is completely voluntary and that I may withdraw from this part of the study at any time.

I have read the foregoing Paper Consent Information Sheet and agree to the terms set out for being a volunteer participant, and I give my consent to have the certified phlebotomist (or nurse or EMT) draw my blood today.

☐ I agree to provide blood samples

☐ I DO NOT agree to provide blood samples

Witness _____

Month: _____ Year: _____

Thank you for your time!

(For those who do not participate)

You were asked to **VOLUNTARILY PARTICIPATE** in an anonymous research study funded by XXXXXXXXXXXXX designed to better understand medication and other drug use among drivers. This type of study is a valuable way to learn how we can improve highway and traffic safety. We respect your right to decline taking part in the breath or blood sample request.

In keeping with our mission of protecting our drivers, I collect observational data on all drivers that enter the study area. If you have concerns about making it to your next location safely, please inform the person who surveyed you before leaving the site. As part of our effort, I am prepared to provide assistance to any drivers to make it to their next location safely.

If you have any additional questions related to this voluntary and anonymous study, you may contact the Principal Investigator, XXXX, at (XXX) XXX-XXXX.

Oral Fluid Verbal Consent (Read aloud)

“We are asking individuals to voluntarily provide a saliva sample. This will only take a few minutes and involves placing one of these pads in your mouth (show device). The saliva will be analyzed later in a lab, and the results cannot be linked to you in any way. You may stop participating at any time. If you provide the sample, you will be paid \$10. Do you have any questions right now that I can answer? Are you willing to participate in this part of the study?”

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Blood Draw Verbal Consent (Initial consent read aloud)

“We are also asking individuals to give a blood sample for this study. To participate in the blood draw, you must not be taking any blood thinners (like Coumadin), or receiving injections such as Calciparine or Liquaemin, and not have a blood disorder such as hemophilia. If you provide the sample, you will be paid \$50. The purpose is to measure some blood components that may be related to driving safety. This is completely anonymous and the results are sent directly to the lab and analyzed. There is no way the results can be matched with you. Leftover blood may be stored for up to 2 years, then destroyed. No genetic testing will be done.

I am a licensed phlebotomist (nurse or EMT) and it takes about 5 minutes. Do you have any questions right now that I can answer? Are you willing to participate in this part of the study?”

“I will indicate on my survey that you said”: ☐ YES ☐ NO

Appendix B: Impaired Driver Protocol Example

Establishing Fitness to Complete Survey and/or Operate a Motor Vehicle

To establish if a driver is fit to complete the study, as well as safely operate a motor vehicle upon exit, use this approach.

- Level 1 - There is no evidence of substance (alcohol or drugs) use, or other impairment.
- Level 2 - There is some evidence of use (e.g., the interviewer can smell alcohol around the driver) but the respondent displays no signs of intoxicated behavior, such as slurred speech or bloodshot eyes.
- Level 3 - There is evidence of use and signs of intoxication. At Level 3, the data collector will determine whether the interview should proceed, and whether the participant needs assistance. The survey will not be conducted on obviously-inebriated or severely impaired individuals. The team leader will offer safe transportation alternatives for these drivers to their next destination.

There will be cases where the participant will show signs of impairment, but is fit to complete the study. The criteria for participation are that the driver can understand the informed consent process and is able to provide informed consent. The person must be able to understand the nature of the study as explained to them, the risks and benefits of participation, and that participation is voluntary. Being intoxicated does not preclude a person from being able to comprehend these basic concepts, and to process this information.

If ability to complete the survey is in question, the data collector will say, “I want to make sure you understand what this study is about so, before we continue, can you explain to me what you think this survey is about? Can you tell me whether participation is voluntary or not?” If the driver cannot explain the study or did not understand that participation was voluntary, the data collection will cease for that driver, and the data collector will implement the Impaired Driver Protocol.

Why This Matters, and Key Points to Remember

The IRB requires the study to ensure the safety of the participants. The goals of the Impaired Driver Protocol include:

- Identifying respondents who may be unable to provide informed consent because they are too intoxicated to understand the risks and benefits of participation.
- Identifying respondents who may be too impaired to operate a motor vehicle safely.

Instructions to Data Collectors on How to Identify Level 3 Respondents

To identify intoxicated participants (Level 3), look for a clustering of the following signs and symptoms. No one sign or symptom is a direct indication of intoxication but when combined, warrant the data collector doing a more in-depth evaluation. Alcohol and other drugs affect individuals differently. The effect will vary according to the person's height, weight, drinking history, mood, the time of day, amount of food in the stomach, etc. Signs of intoxication include the following.

- A strong scent of alcohol, or other drugs
- Being overly friendly
- Talking loudly, bragging, or using foul language
- Being especially annoying or arguing with others
- Slurred or slowed speech or difficulty speaking
- Tending to lose the train of thought
- Glassy eyes, dilated pupils, bloodshot eyes
- Inability to focus, sleepy look, and bobbing head
- Sudden or unexplained mood changes (agitation, anxiety)
- Marked lack of coordination (e.g., inability to find something in the car, unable to hold a pen)
- Confused, disoriented appearance
- Body tremors or perspiring
- Statements suggesting hallucinations

Protocol for Handling an Impaired Driver

An important component of conducting a roadside survey is ensuring the safety of all participants, including impaired drivers. Strategies must be carefully considered to balance safety of entering a data collection location, and the rights of that person to not be unlawfully detained. It is critical for survey managers to consult with legal experts and local authorities on developing an appropriate protocol for the study. The information presented here is as starting point for discussions for individual jurisdictions.

The study will offer safe transportation alternatives to the next destination for any individual who shows obvious signs of substantial impairment and is believed to be unsafe to drive. The driver's behavior, odor, and appearance are indicators a person may be a possible danger to themselves, passengers, or other road users

If the data collector believes the participant is potentially impaired but able to give informed consent, they will explain to the driver they are showing signs of impairment and there is concern about the driver getting to their destination safely. The data collector will be equipped

with a PBT with unmasked BAC numbers, and will request a breath test from the participant. If the BrAC is .05 or above, the data collector will present these options to the participant:

1. Passenger drives

If a passenger has a valid driver's license, it is possible the data collector can give that person a breath test. If the BrAC is .049 or below, and the individual shows no signs of obvious intoxication, the data collector can encourage the passenger can drive. If a passenger is under 21, a lower BrAC threshold of .02 or less (many States have zero tolerance policies for drivers under age 21) may be appropriate.

2. Call a friend or relative of the driver

The data collector can assist the participant in calling a friend or relative of the participant and request someone come and assist the driver. Ideally, two people come so that one can take the participant home, and the other can drive the participant's vehicle. The data collector will request a breath test of the friend or relative, again using a BrAC below .05 as the target level for driving.

3. Offer ride home from taxi or towing service

The project will pay for a cab ride. The participant's vehicle can be left at the location, moved to a nearby parking area, or towed. If using a cab service, the data collector will give the participant the vehicle keys and the address where the vehicle will be located. If a towing service is used, the participant can ride with the tow driver. The study team will have phone numbers for taxi services and for tow companies on hand for each site.

4. Offer to pay for a hotel

If the participant lives too far away for any of the above options, and if desired by the participant, the data collector may arrange for the person to stay in a nearby hotel. The study will pay for a cab ride and a one-night stay.

5. Additional option

If the driver rejects all options, the site manager will talk with the person and discuss the concerns, stressing the person's potential danger to themselves and others. The research team cannot detain the person against their will. The safety officer will be notified and can reiterate concerns to the driver and will repeat the options. If that fails, the safety officer will inform the driver that if the person again enters the road, they could be stopped by law enforcement for impaired driving. Given the study requirement to ensure a safe environment for all in the area, the safety officer would contact local law enforcement to say that an apparently impaired driver is on the road near that location. Ultimately, the decision is the driver's.

Appendix C: Safety Officer Responsibilities

Safety Officer Role

The primary responsibility of the safety officer is to provide overall safety for both survey participants and the research team. Local law enforcement agencies may have restrictions on what off-duty personnel are allowed to do beyond providing general security. For example, some agencies will not allow an officer to assist with sign set up or make any contact with participants unless it is safety related. In general, the safety officer must be prepared to do the following.

- Work with the data collector to identify a safe sampling location
- Assist with location setup (if allowed for off-duty law enforcement)
- Provide safety and security during data collection
- Ensure everyone on the research team is wearing a safety vest, and any other required personally-protective materials
- Remain within sight and sound of data collectors during data collection
- Assist in ensuring that identified impaired drivers get home safely

Human Subjects Training

Safety officers may be required to complete the Human Subjects Training if they have a direct role in data collection (e.g., recruiting participants or serving as data collectors). If the training is required, a certificate of completion must be on file with the project manager.

Safety Officer Procedures

Beginning of Shift

Safety officers and data collectors begin the data collection shift at the meeting place. It takes 15 to 30 minutes to prepare for data collection. The safety officer will:

- Obtain the data collection locations, including mile markers or other physical descriptions. Other information will detail direction of travel to be sampled.
- Check the project vehicles to ensure all safety related materials such as traffic signs, vests, and wands are packed.

Research and Safety Officer Vehicles

One, possibly two, research vehicles or vans will be needed. These vehicles will store materials and transport data collectors. Safety officers, however, will drive to the location in their own vehicle.

Data Collection Location Set-up

Once all the materials and equipment are loaded into the research vehicle, the team will drive to the data collection location. The primary role of the safety officer at set-up is to ensure the data collection arrangement is safe for both the data collectors and the public. If allowed by the local law enforcement agency, safety officers will assist the data collectors in setting up the location.

A location's data collection may be set up as seen in Figure C1.

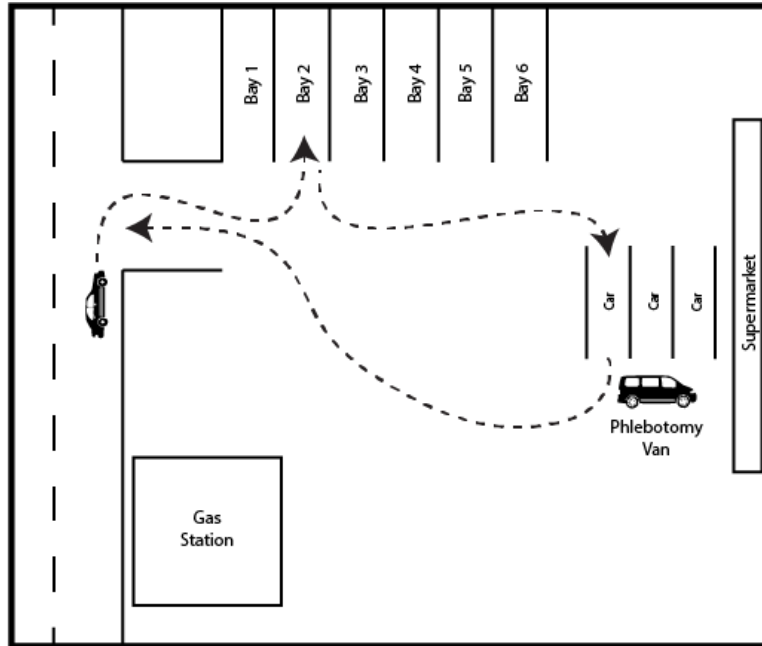


Figure C1. Site sketch

Safety officers must ensure that each location allows for a safe environment for both researchers and participants. Each location is set up (Figure C2) so it clear where a driver drives to for participating. Orange cones can be used to create a path for vehicles. Portable lighting may be needed at night. All data collectors must wear retroreflective safety vests.



Figure C2. Night time data collection

Safety officers are responsible for making sure the traffic signs are set up in a safe and legal manner per local regulations. The signs must be placed in a visible area for drivers approaching the location. They must not obstruct a driver's view of the roadway and not be placed on private property.

- “Paid Voluntary Survey” (Figure C3) should be placed about a block from the entrance of the location.
- “Make up to \$xx,” should be placed about half a block from the entrance.
- “Enter Here to Volunteer” should be placed at the entrance of the location.



Figure C3. Sign placement

The signs should not be visible to drivers until data collection starts, otherwise vehicles may begin entering before start time. When the team is ready, place the signs for drivers to see, and begin data collection for the 2-hour period.

Monitoring Recruitment of Drivers

Data collectors will invite drivers of passenger vehicles (verbally or by waving) into the data collection location. In some instances, data collectors can talk to drivers while they are stopped at the red light or stop sign, but on other occasions data collectors may only be able to use traffic wands to guide drivers to the data collection location. The safety officer monitors the traffic, road conditions, driving speed, and notify data collectors if a change in positions is warranted for safety purposes.

Maintaining Security and Safety During Participant Interactions

The sampling location can get busy when multiple drivers are participating at the same time. As such, it is important that safety officers:

- Maintain visual contact with the data collectors.
- Determine if any drivers are uncomfortable, or if a data collector is uncomfortable with a driver (e.g., by indication of an established sign – such as a hat turned backwards), and determine if it is best for the survey manager to intervene, or if more assistance is needed.

In NHTSA's National Roadside Surveys and in the study in Washington, teams worked through high temperatures, freezing weather, and heavy rain; however, data collection must be halted if there is lightening, or if road conditions are unsafe.

End of Data Collection Session Procedures

The data collection ends at 2 hours. Data collectors finish with any collections in progress, but no new drivers will be recruited. The safety officer remains vigilant while the site manager oversees that all equipment gets packed, starting with the removal of the signs on the road.

Appendix D: Data Collector Responsibilities

Data Collector Role

The role of the data collector is critical as it involves recruiting drivers from free-flowing traffic to participate in the study activities. It is vital to achieve the highest participation rate as possible. Data collectors must: do the following:

- Ensure all equipment is packed and easy to access
- Set up traffic signs
- Recruit drivers from traffic
- Ask drivers if they would like to participate and obtain consent
- Administer components of the study
 - Breath test
 - Oral fluid sample
 - Blood sample
- Enter data on paper forms or into tablet
- Distribute incentives to participant
- Intervene with drivers who are impaired, for any reason, and implement the Impaired Driving Protocol
- Handle all biological samples according to protocols

Human Subjects Training

All data collectors must complete Human Subjects Training. A certificate must be on file with the principal investigator.

Study Supplies and Equipment

It is essential that field supplies be properly maintained and sufficient supplies packed for each data collection shift. Detailed checklists will be beneficial to help data collectors pack supplies. Each data collector is responsible to ensure they have enough supplies available and that all equipment is calibrated (e.g., PBTs) as appropriate.

Data Collector Backpack. Each data collector will have individual supplies, such as a backpack and toolbox (Figure D1). Table 1 lists common items that would be included in a backpack. The backpack can contain an accordion file folder for all paperwork, and a computer tablet if one is being used (Table D2).



Figure D1. Data collector's survey bag and toolbox

Table D1. Common Contents of a Data Collector's Back Pack

Item	Quantity
Tablet	1
Portable Breath Tester (PBT)	1
Breath Tubes	At least 1 bag of 25 tubes
Batteries for PBT	6
Reflective (Safety) Vests	1
Medical Masks	6
Medical Gloves	30
Lab Coat (phlebotomist)	1
Research Team Hat	1
Side Bag for Supplies	1
Headlamp	1
Money Holder	1
Paperwork Accordion Folder	1
Blood Draw Consent Form	10
Paper Participation Forms	30 each

Table D2. Paperwork and Supplies in Accordion Folder

Item	Quantity
Interview Packet	20
Clipboard	2
Pens	1 box
Blood Draw Consent Form	10
Participation Form	20
Phlebotomy Incident Report	5

Oral Fluid and Phlebotomy Toolbox. A toolbox (Figure D2) can hold all oral fluid and blood draw supplies. Each data collector is responsible for maintaining and organizing the toolbox. Common contents of the toolbox are shown in Table D3.



Figure D2. Contents of the oral fluid and phlebotomy toolbox

Table D3. Contents of the Toolbox

Item	Quantity
Grey Top Blood Collection Tubes	10
Gloves	1 box
Tourniquets	10
Antiseptic Wipes	10
Band-Aids	10
Sterile Gauze Pads	1 box
Butterfly Needles	10
Eye Wash	1
Chain of Custody Label Booklet	2
Straight Needles	10
Vacutainer	10
Biohazard Spill Kit	1
Headlamp	1
Hand Sanitizer	2 bottles
Clorox Wipes	1 container
Absorbent Pads	30
CPR Mask	1
Oral Fluid Kits	10

Coolers for Biological Specimens. Each biological specimen cooler (Figure D3), will be packed with the supplies listed in Table D4.



Figure D3. Storage cooler

Table D4. Contents of Cooler for Biological Specimens

Item	Quantity
Sharps Container	1
Cold Packs	5
Red Specimen Container	1
Absorbent Pads	5
Eye Wash	1

Additional Supplies and Equipment. A variety of other supplies and equipment are needed for data collection as shown in Table D5. It is beneficial to have water and light snacks for participating drivers and their passengers. To keep passengers or pets content while drivers complete the process, supplies such as coloring books and dog treats are useful. Once a driver has agreed to participate, it is important to make the process as easy as possible for them to complete the survey.

Table D5. Additional Supplies and Equipment for Data Collection

Item	Quantity
Traffic Signs	3
Traffic Sign Stands	3
Traffic Wands	8
Garbage Bags	1 box
First Aid Kit	1
CPR Masks	5
Biohazard Spill Kit	2
Team Jackets	2
Safety Vests	3
Rain Ponchos	4
Umbrellas	2

Research Vehicle. An assigned data collector will drive a research van to transport the team and supplies to data collection locations. All team members should travel together. For each data collection one or more of the data collectors coordinate with the team leader to:

- Check that all supplies are packed securely in the vehicle,
- Check that the van has sufficient gas, and
- Ensure everyone is wearing a seat belt.

General Safety and Other Special Considerations

A primary consideration of this project is the safety of everyone involved in the study including the research staff, participants, passengers, and safety officers. Data collectors should always be alert and vigilant. An activity should not be conducted if it cannot be done safely. Adherence to the following guidelines will help keep the data collection safe for everyone:

- Everyone on the team, including any study observers, must wear a reflective vest.
- Each data collection bay is clearly marked with orange traffic cones. Cones with lights (Figure D4) are beneficial for nighttime events.
- No member of a team will get into a participant's vehicle.
- If a data collector suspects a driver may be intoxicated, they will implement the Impaired Driver Protocol.
- If a data collector sees a weapon in the vehicle, they calmly dismiss the driver by indicating they do not meet the study's criteria. The data collector will not take any action that might appear to attract attention to that driver. After the car has left, the data collector reports the incident to the safety officer.
- If a data collector feels threatened or is being abused by a participant (or passenger), the data collector concludes the interview in a friendly manner and instruct the driver to exit.
- If reporters or passersby come into the area and begin engaging in conversation, the data collector will ask to speak to the person away from data collection, and explain the survey requires the anonymity of subjects. It is beneficial to have a "Frequently Asked Questions and Answers" document ready for reporters and others, with contact information for the Principal Investigator.
- Data collectors guide drivers in and out of bays. As a vehicle enters the bay, maintain a safe distance to allow room for the car to maneuver and do not approach the driver until the vehicle has stopped. Before a driver leaves, make sure the area is clear of equipment, people, and other vehicles pulling out of neighboring bays/parking stalls.
- Keep a list of phone numbers for cab companies, tow companies, hospitals, and the principal investigator.

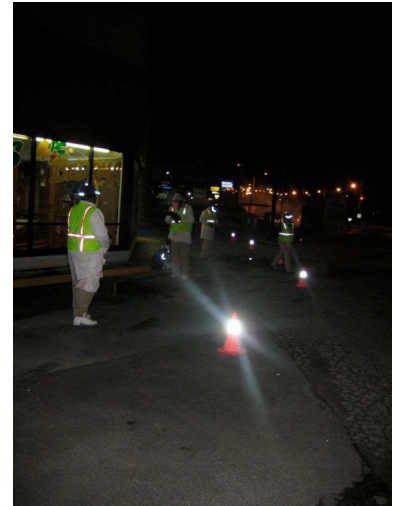


Figure D4. Cone with Light

Data Collection Considerations

The quality of a data collector's work is as important as the quantity. An interview with incomplete or out of range data may need to be discarded. To minimize bias, data collectors need to follow the study script with all aspects of the collection completed in the same order and manner for every participant. Even small changes in intonation can change the meaning of the question to a participant, or affect the way a participant responds to a request for a biological sample. It is important to note that:

- All consent scripts and procedures must be followed exactly as planned.
- A participant can stop data collection at any time.
- A data collector does not alter the way a question or biological sample request is worded, even if it feels like the question or request is getting at the wrong information or is not understood.
- If a data collector feels a question is continuously misunderstood by drivers, they will notify the Principal Investigator.
- If something critical is missed (e.g., forgot to conduct breath test), it is okay to go back and gather the information if the participant is still willing to continue.
- Do not omit any of the questions or requests, even if it seems obvious how the subject will respond based on previous responses. The study wants their answers, not the data collector's perception of how they think a participant will answer.
- If the participant is talking freely, it may feel like some of the questions or biological sample requests have already been answered. Before reading the question or request, the data collection should say something such as, "You already mentioned this, but I do not want to assume your response."

Confidentiality. Although it is unlikely a data collector will encounter anyone they know while collecting data, it could happen. If this occurs, switch to another data collector who does not know the individual. Importantly, a data collector cannot accept any identifying information, such as names and phone numbers, from participants. Participants must remain anonymous. Likewise, a data collector cannot hand out their own information.

Questions or Complaints. As a driver leaves the data collection area, they should be given an information flyer. The flyers can be different depending on whether the driver participated or declined. The flyer should contain information about the study, the protocols, and contact information for questions or concerns. If a driver has a complaint during the data collection, the data collector makes a note and informs the team leader.

Incidents. Data collectors keep a record of anything out of the ordinary that occurs at a data collection location. This includes interactions with participants, the public, media, other data collectors, or anything else that falls outside of normal operating procedures. The team leader is notified immediately of such incidents.

Media. Data collectors must not speak with members of the media. If a data collector encounters any members of the media, they will be referred to the team leader on site who will provide them with the Frequently Asked Questions and Answers sheet. If cameras are seen on site, all data

collection must temporarily stop to protect participant confidentiality. Data collection can resume once the media members leave.

Social Media and Photos. It is common for drivers and passengers to immediately send word to friends and family about the data collection through text messages or social media. To ensure anonymity of all participants, data collectors can ask vehicle occupants to refrain from taking photos or videos of other vehicles or participants. It is equally important for team members to avoid sending information about the location of data collection to anyone in the area, or to take photos or videos of participants. Data collectors must not share information about the event on social media.

Increasing Participation Rates. It is important to gather as many samples as possible at each data collection location. If approved by the study's IRB, a data collector may be able to offer an additional incentive to drivers who initially decline to participate. This generally involves asking if the driver would be willing to reconsider their decision, for a larger incentive (i.e., more money in addition to the original dollar amount offered). For a participant to be considered a "conversion" and receive the additional incentive, they must complete the full survey. The wording follows the approved protocol and may include something such as, *"It's really important for us to get as many blood samples as we can, so I'd like to offer you an additional \$20, on top of the original \$50 if you would be willing to participate in this portion of the study."* These respondents need to be recorded as conversions for data analysis purposes. Again, this approach can only be used if approved by the IRB.

Data Collection Procedures

Beginning of Shift Procedures. The team meets and at least one hour before data collection to:

- Confirm data collection locations.
- Check the vehicle to ensure sufficient fuel.
- Confirm individual data collector's equipment is packed – match against list of supplies.
- Confirm team equipment is packed – match against list of supplies.
- Allocate incentive payment funds to data collectors.
- Log in and sync data collection devices.
- Ensure PBT and tablets are working and have sufficient battery. Replace batteries or charge devices.
- Confirm contact information for cab companies.

Data Collection Location Set-Up. Try to arrive at 30 minutes before data collection. Under the direction of the team leader, the data collectors set up the location (Figure D5) for recruited vehicles to park and determine where the research vehicle and the safety officer's vehicle will be positioned. Once an interview area has been set, data collectors must:

- Put on personal protective supplies, such as masks, face shields, and gloves. Wear a retroreflective safety vest.
- Using the sketch from location selection, set up the entrance and exit.
- Organize supplies in order of use (breath tubes, tablet, PBT, incentive funds, etc.).
- Log in to any devices.



Figure D5. Site set-up

Placing signs. Typically, at least three large, diamond-shaped project signs are used at each location. The signs must be visible to approaching drivers. They must not obstruct a driver's view of the roadway and must not be on private property. Signs are placed as follows:

- “Paid Voluntary Survey Ahead” about a block from the entrance of the location.
- “Make up to \$xx,” about half a block from the entrance.
- “Stop Here to Volunteer” at the entrance.

The signs are not be placed until data collection starts, otherwise vehicles may begin entering before start time. Immediately before data collection begins, the team leader takes photos or a video to document location of data collection, and the signs. This is useful if a driver disputes the study was voluntary or if another issue arises.

Recruiting Drivers. In some instances, data collectors can talk to drivers while they are stopped at a red light or stop sign, but on other occasions data collectors may only be able to use traffic wands (Figure D6) to guide drivers to the data collection location. If speaking is possible, a data collector can explain that they are recruiting drivers to participate in a voluntary paid research study. The data collector waving in participants continues until all bays are full. Recruiting pauses until a bay is open to avoid having participants wait.



Figure D6. Recruiting

Be cautious to not recruit drivers of excluded vehicle types, such as commercial vehicles.

Initial Driver Demographic Observations. As a driver enters a bay, the data collector will record initial observational data, such as vehicle information and demographics.

Approaching the driver. Once the driver has parked, a data collector will greet the driver and ask them to turn off the vehicle. If the driver agrees to participate, the data collector will begin the consent process. Every driver must hear the same information, and be treated in a professional manner.

If there is a self-administered component, (e.g., self-reported medication use), the data collector steps slightly away, so the driver does not feel their responses are being watched.

Breath Sample. The data collector will use a PBT to estimate a participant's BrAC. PBTs measure BrAC by use of a fuel cell inside the instrument. For these types of studies, it is common to mask the breath test results and later download the results. The data collector will read the consent script for the breath sample consent to a driver, and record the response. Example instructions are below. Procedures may need to be modified if conditions such as COVID-19 are a factor.

1. The display begins with "Please Blow." The PBT sample number will be displayed." Tell the driver, "Please take a deep breath and blow slow and steady into the tube until I tell you to stop."
2. Remove the disposable mouthpiece from its wrapper, making sure not to touch the end into which the participant will be blowing. Also, within sight of the participant, pull the wrapper off. This allows each driver to know the mouthpiece is sanitary.
3. Attach the disposable mouthpiece to the mouthpiece holder. Position the mouthpiece away from the data collector.
4. Position the PBT just in front of the participant's mouth and let the person know when to start. If the participant has difficulty understanding the request, demonstrate taking a deep breath and exhaling steadily for few seconds.

5. The participant continues to blow into the breath tube. A “click” will occur when the participant supplies enough sample of breath. The actual result will not appear.
6. If the participant does not provide an adequate breath sample on his or her first try, “TEST AGAIN” will appear on the screen. Explain the directions again to the participant and attempt to capture the breath sample.
7. Once a breath sample has been taken, thank the participant.
8. At the end of each breath sample, remove the used breath tube, place it in the trash, and record the PBT sample case number.

Taking a Manual Reading. Under normal conditions, the PBTs are designed to capture a sample automatically by measuring the duration and strength of air flow past a sensor. Some participants may not be able to provide a sufficient breath sample for the PBT. In these cases, the data collector must obtain a “manual reading”:

When the PBT is ready to take a sample, ask the participant to blow into the breath tube. Pressing down on the button (Figure D7) while the participant is blowing will capture the reading. The data collector waits as long as possible before pressing the button because the reliability of the BrAC improves with sustained breath.



Figure D7. Taking a manual reading during training session

Proper PBT Care. PBTs are sensitive equipment and require special care. Follow the recommendations below to make sure the device is working as intended.

1. If any warning sounds, lights, or messages appear while using the PBT, switch to a backup device.
2. Protect devices from rain or other moisture.
3. If a PBT is dropped, switch to another device. The original one must be recalibrated.
4. Cigarette smoke can permanently damage the fuel cell. Instruct participants to extinguish any cigarette, and not chew anything for two minutes prior to collecting the breath sample.

Oral fluid. Upon completion of the breath sample collection, the data collector will read the consent script for requesting an oral fluid sample, and enter the response. If the participant agrees

to provide a sample, they are given the device to put in their mouth to collect a saliva sample. The following is an example of the instructions:

1. Place the package in front of the respondent and ask, "Please remove the collector from the pouch, position it under your tongue and close your mouth."
2. "Please DO NOT chew or suck on the pad and do not move the pad during collection. Keep the pad under your tongue until I indicate there is sufficient sample; this may take a few minutes."
3. Ask the participant to remove the collector from the mouth and insert the collector into the holder.
4. Place a label on the tube and enter the chain of custody number into the tablet.
5. Mix the saturated collector with buffer fluid by gently shaking tube. Return the oral fluid sample to the kit for storage.
6. Provide the respondent with the incentive for their participation.

Blood Draw. The data collector will read the consent script for a blood sample to the driver and record the response. For participating drivers, the data collector will give the person a copy of the blood consent form. The data collector must go over each item on the form and answer any questions. The data collector then escorts the driver to the phlebotomy van or asks the phlebotomist to come to the vehicle to take the sample. Once collected, the blood sample tube must be placed in the specimen container in the cooler.

Concluding the Interview. Provide incentive funds, and answer any questions.

End of Data Collection Session Procedures. The research team must:

- Store oral and/or blood samples in specimen containers, along with ice packs, etc.
- Re-pack all supplies.
- Re-pack the research vehicle.
- Scan the area to ensure that any trash is picked up and make sure to leave the area as clean as when the research team arrived.
- Fill out an incentive disbursement form. This is an important step in accounting for the money a data collector received and distributed.

Appendix E: Phlebotomist Responsibilities

Meet the research team before data collection, check for all supplies, and pack the phlebotomy equipment into the study vehicle.

When you arrive at a location, assess the layout. You must create a phlebotomy station that is safe, comfortable, hygienic, and with sufficient lighting. The process may involve having the subject sit in the study vehicle, but this is not necessary if a portable chair is available and there is a place to rest an arm. The collection station must be positioned to be seen by the data collection team, safety officer, and drivers.

When data collection begins, and as participants volunteer for the blood sample component, conduct blood draws according to protocol, and according to your own phlebotomy training.

- Wear scrubs so subjects recognize you as a medical professional.
- Wear gloves and other safety materials.
- Identify yourself as a certified phlebotomist (nurse, or EMT).
- Explain the blood collection procedure to the subject, and explain any risks.
- Confirm the person's age is eligible for participation-requirements vary across States.
- Request the subject's consent on the consent form.
- Conduct the blood draw.
- You may offer a piece of candy or light snack.
- Regardless of the amount of blood taken, even if an incomplete sample, provide the incentive for participation.
- Maintain participant anonymity. Report any problems to the data collection manager.
- Ensure samples are handled and stored in accordance with site rules, as well as all applicable laws and regulations.

Throughout data collection, assist others in storing oral fluid samples. Store the blood samples in coolers or other designated containers. These must be in a safe location where there is no chance they can be run over by a vehicle.

As data collection ends, break down your equipment and pack it into the study vehicle. Ensure all hazardous materials are disposed of safely and in accordance with applicable laws and regulations. After data collection sessions, assist the data collection manager in packing the biological samples for shipping to the toxicology lab.

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